Foodborne Diseases Active Surveillance Network (FoodNet) Surveillance Protocol, 2004

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Active Surveillance Protocol

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I. ACTIVE SURVEILLANCE OBJECTIVES

1. Determine the incidence and clinical consequences of foodborne diseases in the United States
2. Monitor change in incidence in foodborne diseases over time

II. INTRODUCTION

The Foodborne Diseases Active Surveillance Network (FoodNet) is the principal foodborne disease component of the Centers for Disease Control and Prevention's (CDC's) Emerging Infections Program (EIP). FoodNet is a collaborative project among CDC, the eleven EIP sites, the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA), and the United States Food and Drug Administration (FDA). FoodNet augments, but does not replace, longstanding activities at CDC, USDA, FDA, and in states to identify, control, and prevent foodborne disease hazards.

FoodNet is a sentinel network that is producing more stable and accurate national estimates of the burden and sources of specific foodborne diseases in the United States through active surveillance and additional studies. Enhanced surveillance and investigation are integral parts of developing and evaluating new prevention and control strategies that can improve food safety and health. Ongoing FoodNet surveillance is

being used to document the effectiveness of new food safety control measures, such as the USDA–FSIS Pathogen Reduction and Hazard Analysis and Critical Control Point (PR/HACCP) systems, in decreasing the number of cases of foodborne diseases that occur in the United States each year.

III. ACTIVE SURVEILLANCE DATA– LABORATORY CONFIRMED CASES

A. CASE DEFINITION

Isolation of laboratory-confirmed *Campylobacter*, *Cryptosporidium*, *Cyclospora*, Shiga toxin-producing *E. coli* (including *E. coli* O157), *Listeria*, *Salmonella*, *Shigella*, *Vibrio*, and *Yersinia* from a resident of the catchment area during a given time period (e.g., calendar year)

B. DATA COLLECTION

FoodNet personnel within each site contact each clinical laboratory within that site's catchment area either weekly or monthly, depending on the laboratory size. Sites ascertain all laboratory-confirmed cases (see section titled "Case Definition") of infection from stool, and sites also ascertain all laboratory-confirmed cases from urine, blood, cerebrospinal fluid, or other sterile sites (e.g., bone, joint fluid, or peritoneal fluid). Of note, isolates from urine were not included in FoodNet surveillance from 1996 to 1998, *Cryptosporidium* and *Cyclospora* were not included

in FoodNet surveillance in 1996 and 1997, and non-O157 Shiga toxin-producing *E. coli* were not included in 1996 and 1999. Additionally, each clinical laboratory within that site's catchment area should be audited at least twice per year (see section titled "Clinical Laboratory Audit") to evaluate the completeness of case ascertainment.

A person with the same pathogen isolated 2 or more times from the same specimen source within a thirty day period (regardless of calendar year) will be identified as a duplicate and the second isolation will be excluded from the active dataset. Persons with the same pathogen isolated from the same specimen source within 31 to 365 days of the original culture (regardless of calendar year) will be classified as a carrier and the second isolation will be excluded from the active dataset.

Of note, it is possible that a resident within the FoodNet catchment area may become ill, seek medical care and submit a specimen, but that the specimen may be sent to a clinical laboratory that is geographically outside the FoodNet surveillance area. FoodNet attempts to ascertain such cases by contacting the larger diagnostic reference laboratories that are likely to receive specimens from residents of the FoodNet sites. Those clinical laboratories outside the surveillance area that have been identified as having received specimens from FoodNet residents are then added to the list of clinical laboratories that are routinely contacted by FoodNet surveillance officers within each site.

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Once a case has been identified, FoodNet personnel within each site complete a Case Report Form and/or enter the data directly into an electronic database. The Case Report Form should serve as a template for the information to be collected. If the appropriate information is being captured, a hard copy of the Case Report Form does not necessarily need to be completed. There is one Case Report Form for bacterial pathogens (Appendix I) and one Case Report Form for parasitic pathogens (Appendix II). Definitions for these variables can be found in Appendix III. The information from these forms is compiled by each site within an electronic database (see section titled "Database Structure").

In 2004, there were two major changes to the data collected by FoodNet. First, FoodNet began identifying whether a case was part of a foodborne outbreak and, if so, what the Electronic Foodborne Outbreak Reporting System (EFORS) number of that outbreak was. Second, FoodNet began collection international travel history for cases. The exposure window asked varied depending on the pathogen. For *Salmonella* Typhi and *Listeria*, cases were questioned about travel in the previous 30 days before their isolation date. For *Cryptosporidium* and *Cyclospora*, cases were questioned about travel in the previous 15 days before their isolation date. For all other FoodNet pathogens, cases were questioned about travel in the 7 days before their isolation date.

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C. DATABASE STRUCTURE

FoodNet surveillance data should be housed in an electronic data management system. Historically, FoodNet sites have used the Public Health Laboratory Information System (PHLIS) to store data on-site and to transmit data to CDC. In 2002, FoodNet personnel determined that PHLIS was not necessarily the best method for storing and transmitting data for FoodNet purposes. FoodNet will eventually switch to the National Electronic Disease Surveillance System (NEDSS) and is currently developing a Foodborne Program Area Module (PAM). We hope these changes will be implemented in 2004.

Until NEDSS is implemented, each site has developed a method for data storage and transmission that meets the needs of that site. California, Connecticut, Georgia, Minnesota, and Tennessee have and will continue to use PHLIS to store FoodNet data until NEDSS is implemented. Colorado, Maryland, New York, New Mexico, and Oregon use state-based data structures that are NEDSS compliant to store FoodNet data. All FoodNet sites transmit data on a monthly basis to a secure FTP website at CDC.

Regardless of the data structure (i.e., PHLIS, a NEDSS-compliant state developed system, NEDSS), data should contain the same basic information. Variable names, definitions, and legal values can be found in Appendix IV.

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D. DATA TRANSMISSION

FoodNet surveillance data are transmitted to CDC on a monthly basis. An email is sent out a few weeks before the Steering Committee conference call reminding sites of the deadline for monthly data submission. Steering Committee calls are held on the second Thursday of each month. It is strongly encouraged that sites follow this deadline as a lack of timeliness delays the monthly review and analysis of data. Year-to-date numbers should be submitted with each transmission. FoodNet sites are requested to post their data on the secure FoodNet FTP site and inform the appropriate CDC surveillance officer when these data have been posted. After these data are downloaded from the FTP site, the file is deleted from the site.

E. DATA MANAGEMENT AT CDC

A patient with multiple isolates will require one or several Case Report Forms, depending on the situation.

A. *Time Frame*: If a patient has been identified as a duplicate as described above, a new Case Report Form is not needed. For example, if *Salmonella* is isolated from two stools specimens in the same week, only enter the first isolate into the database. This will be counted as one case in any analyses. If a patient has been identified as a carrier as described above, a new Case Report Form is needed. For example, if *Salmonella* is isolated from stool on the first of the month and a second *Salmonella* is isolated from stool on the fifteenth of the following month, enter both stools into the database.

B. Multiple Sites: If the patient has the same pathogen isolated from different specimen sources, regardless of the time, then a new Case Report Form is needed for each source. For example, if *E. coli* O157 is isolated from blood and stool, enter both into the database. This will be counted as one case in analysis and the more invasive specimen will be used for analysis.

C. Multiple Specimens: If the patient has multiple pathogens, or the same pathogen with different serotypes, isolated from the same source, regardless of time, then a new Case Report Form is required for each pathogen. For example, if *Campylobacter* and *Shigella* are isolated from stool, then enter both pathogens into the database. These will be counted as two cases in analysis.

F. DATA CLOSE-OUT

Preliminary data close-out begins in January and continues into February in time for the annual FoodNet Morbidity and Mortality Weekly Report (MMWR) which is published in the April. Final data close-out begins in late June and continues into July. During preliminary and final data close-outs, each site works with a CDC surveillance officer to reconcile case counts between CDC and the sites.

By mid-June, sites should have all cases for the previous year entered into their databases, these data should be sent to CDC (in that data transmission, each site should also provide information on a summary of the case counts, the number of

carriers, whether carriers are included in these data, and whether duplicates are included in these data). After these data are received, a CDC surveillance officer will begin checking cases counts (i.e., CDC case counts compared to individual site cases counts). By middle of July, CDC and each site should have reconciled final case counts. Each site should send an official email stating their final counts, by pathogen, for that year.

Once CDC and the sites have agreed on the case count numbers, CDC surveillance officers will review these data. Any data that may seem errant will be flagged and the site will be asked to verify the data point. If changes to the data are necessary, the data should be resubmitted and case counts should be re-verified.

G. DATA QUALITY

Surveillance officers at CDC perform monthly checks of all surveillance data to ensure quality and completeness. In this process, the surveillance officers run frequencies on the data to look for any outlying data points (e.g., AGE=129 years). If any outlying data points are identified or if there are questionable data points, CDC will contact the site and request a correction or verification. For a correction to be utilized, data corrections must be made at the site and cleaned data must be retransmitted.

In particular, the surveillance officer will focus on accuracy of *Salmonella* serotyping data and accuracy and completeness of the State Laboratory Identification Number (SLABSID) (see section titled "FoodNet/NARMS integration"). The CDC surveillance officer will contact sites on a prospective basis, about inaccuracies or incomplete information. Changes made to the data at the sites will be captured during the next monthly transmission.

Additionally, the FoodNet Performance Standards (Appendix V) have been developed to assess completeness and accuracy of FoodNet data. Twice a year, these standards are evaluated and feedback is provided to the sites. Performance standards are reviewed annually at the Coordinators Meeting and revised as appropriate.

H. FOODNET/NARMS INTEGRATION

The National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS) was established in 1996 within the framework of the CDC's Emerging Infections Program's (EIP) Epidemiology and Laboratory Capacity Program. NARMS collaborators include CDC, FDA, and all state and selected local health departments. The primary objective of NARMS is to monitor antimicrobial resistance among *Salmonella*, *E. coli* O157, and *Shigella*. Participating sites forward every twentieth non-Typhi *Salmonella*, *E. coli* O157, and *Shigella* isolate as well as every *Salmonella* Typhi, *Listeria*, and *Vibrio* isolate to CDC. Once the isolates arrive at CDC, microbiologists test them for susceptibility against 17 antimicrobial agents.

NARMS and FoodNet personnel at CDC have been working towards linking data from both surveillance systems, thus integrating susceptibility data from NARMS with patient data from FoodNet. Eventually, the goal is to also integrate data from the National Molecular Subtyping Network for Foodborne Disease Surveillance, also known as PulseNet, to improve the power of all 3 surveillance programs.

For FoodNet and NARMS data to be linked, each isolate must have a unique identifier, which is the State Laboratory Identification Number (FoodNet variable: SLABSID). We encourage FoodNet epidemiologists to communicate with the NARMS microbiologists in each state to make sure that FoodNet data and NARMS isolates from the same patient are identified by the same State Laboratory Identification Number. At CDC, surveillance epidemiologists will prospectively monitor monthly FoodNet data submissions to ensure the correct State Laboratory Identification Number format is being submitted. If a case is submitted with an incorrect State Laboratory Identification Number format, the case will be "flagged" by the FoodNet application and CDC FoodNet personnel will contact the appropriate site to request a correction.

I. CLINICAL LABORATORY AUDIT

Regular clinical laboratory audits are a fundamental requirement of FoodNet active surveillance of laboratory confirmed cases. To ensure that all cases of diseases under surveillance are being reported and to ensure that any change in incidence is not due to surveillance artifacts, audits of every clinical laboratory within the FoodNet

surveillance area must be performed at least twice per year. However, if a laboratory routinely reports all culture results via computer printouts, there is no need to repeat the audit, as this method itself meets the criteria for an audit. Hospital visits and/or phone calls may still be necessary to collect information missing from the Case Report Form.

The primary data source at every reporting site (usually a laboratory log slips/log book or computer printout that lists all isolates) should be reviewed for pathogens under surveillance, and compared to the list of cases reported prospectively to the surveillance coordinator. A Case Report Form should be completed on all newly identified cases that have not been entered into the surveillance database. Audits should be performed every January and July for the previous 6 months. Cases identified by audit should be submitted following the FoodNet case ascertainment guidelines used for cases obtained through non-audited methods. Complete Case Report Forms on both "audit" cases and any other outstanding cases should be entered into the computer database by March 1 and September 1 for the audited six-month period. If complete Case Report Forms cannot be entered into the database by these deadlines, basic demographic information such as age, sex, race and county of residence should be entered into the database for these pending cases.

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Acceptable methods for auditing a laboratory include:

- Physical visit by an agent of the state (e.g., FoodNet/state employee, academic partner) to the laboratory to review, in person, the laboratory testing log slips/log books (onsite review). If used, this method must include personal review of every possible positive laboratory test result from the laboratory being audited.

- Review of a computer generated line list of all laboratory data, with documentation that the program used to generate the computer generated list will include every case potentially fitting the FoodNet surveillance definition from that laboratory.

- Review of an electronic database of cases received electronically or in hard-copy from clinical laboratories, with documentation that the program used to generate the database will include every case potentially fitting the FoodNet surveillance definition from that laboratory.

Unacceptable methods for an audit include:

- Sending a list of FoodNet cases to the clinical laboratories for the laboratories to review and indicate whether FoodNet site has counted all cases

- Review of a list of "cases" or positive test results generated by hand, or by review of computer reports, from laboratory personnel, infection control, or other hospital staff.

- Review of cases or positive reports set aside or sent in by laboratory personnel, infection control staff, or other hospital staff.

J. ADDITIONAL COMMENTS ON SELECTED PATHOGENS UNDER SURVEILLANCE

1. Shiga toxin-producing *E. coli*

As FoodNet has gained a better understanding of surveillance for Shiga toxin-producing *E. coli* (STEC), the classification for STEC cases has changed. From 1996-1999, surveillance was only conducted for *E. coli* O157. In 2000, surveillance was expanded in some states to non-O157 STEC and cases were classified into two categories: "*E. coli* O157" and "*E. coli* other." In 2001, STEC cases were classified into two categories: "*E. coli* O157" and "Shiga toxin-producing *E. coli* non-O157". Beginning in 2002, STEC cases were classified into three categories: "*E. coli* O157",

"Shiga toxin-producing *E. coli* non-O157", and "STEC O-Antigen Undetermined."

The classification of STEC into these categories depends upon a number of factors, including whether the isolate was biochemically identified as *E. coli*, the *E. coli* O antigen number, the H antigen number, and the results of the Shiga Toxin Test (Appendix VI).

Isolates are classified as "*E. coli* O157" when a laboratory confirms the expression of the O antigen 157 and either the expression of H antigen 7 or the production of Shiga toxin. Isolates are classified as "STEC nonO157" when a state public health laboratory confirms that the isolate does not express O antigen 157 and that it does produce Shiga toxin. These isolates should be forwarded to CDC for serotyping. If CDC confirms the expression of some other O antigen (e.g., O111, O26), then that O antigen number should be entered, by the state, into the database. Finally, isolates are classified as "STEC O Antigen Undetermined" if a state public health laboratory confirms the production of Shiga toxin and rules out the expression of O antigen 157, and, after testing at CDC, an O antigen cannot be determined.

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2. *Listeria*

In FoodNet, *Listeria* cases are unique from other pathogens in that additional information, including pregnancy status as well as fetal outcome, is collected.

Additionally, the Council of State and Territorial Epidemiologists (CSTE) adopted a *Listeria* case surveillance position statement at their 2003 annual meeting. In this initiative, CSTE recommends prospective, routine interviewing of all listeriosis cases, using a standardized questionnaire, of all patients with culture-confirmed listeriosis. As a result, FoodNet sites began collecting these in 2004. Until this activity can be incorporated into the NEDSS program area module for foodborne diseases, this will be a paper-based reporting system. (Appendix VII) There will be a data entry screen in NEDSS for the *Listeria* Case Report Form.

3. *Salmonella*

FoodNet attempts to record complete *Salmonella* serotype information. In January 2003, CDC adopted the Kauffman White scheme of *Salmonella* serotyping (prior to 2003 the modified Kauffman White scheme was used). *Salmonella* serotype information is submitted to FoodNet during monthly data transmissions. This information is updated as additional laboratory testing is completed. For a list of serotype designations which

vary between the modified Kauffman White scheme and the Kauffman White scheme. Additionally, the documents found in Appendix VIII and Appendix IX will help elucidate *Salmonella* serotype designation.

Surveillance for *Salmonella* Typhi infections is conducted as part of routine FoodNet surveillance. In addition to this routine activity, an additional Case Report Form (Appendix X) for every *S.* Typhi case should be completed. The person originally reporting the illness (e.g., a health care provider) should complete the report and send it to both state surveillance personnel and CDC's Foodborne and Diarrheal Disease Branch at the provided address.

4. *Vibrio*

Surveillance for *Vibrio* infections is conducted as part of routine FoodNet surveillance. An additional Case Report Form (Appendix XI) for every *Vibrio* case should be completed. The person originally reporting the illness (e.g., a health care provider) should complete the report and send it to state surveillance personnel and to CDC's Foodborne and Diarrheal Disease Branch at the provided address.

5. *Yersina*

FoodNet began collection *Yersinia* species information in 2003. An attempt has been made to ascertain this information for the 1996-2002 *Yersinia* data.

V. ACTIVE SURVEILLANCE DATA – HUS CASES

Population-based surveillance for Hemolytic Uremic Syndrome (HUS) was initiated in FoodNet to monitor long term trends in this important outcome of Shiga toxin-producing *Escherichia coli* (STEC) infection, to identify STEC strains that cause HUS in the United States and monitor changes in their frequency over time, and to establish a platform for conducting future studies of HUS pathogenesis and treatment.

The HUS surveillance system is based on reporting by pediatric nephrologists who are requested to promptly report all cases of HUS to the FoodNet HUS surveillance officer within each site. Additionally, several FoodNet sites review hospital discharge data to ascertain pediatric and adult cases of HUS. Review of hospital discharge data is done on a retrospective basis and these data are often not available until 6 months after the end of the calendar year.

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There are three forms associated with HUS surveillance. The first form, the Case Report Form (Appendix XII), should be completed to collect demographic information and data needed to confirm the diagnosis of HUS. Data for the Case Report Form may be collected by interviewing the attending physician, their designee, and/or by reviewing the patient's medical record. The second form, the Microbiology Report Form (Appendix XIII), collects information on specimens that may have been obtained as part of regular medical care. The third form, the Chart Review Form (Appendix XIV), collects information on the outcome and complications of the patient's acute illness. Data from these three forms are entered by each site into an Epi Info database using customized data entry screens. In addition to transmitting the data to CDC on a monthly basis, data are transmitted when a case is identified or new information is obtained for a reported case. For more detailed information on how to conduct HUS surveillance, please review the "Active surveillance for Hemolytic Uremic Syndrome (HUS) Protocol" (Appendix XV).

Serologic testing for *E. coli* O157 and/or *E. coli* non-O157 antigens is available at CDC. Because the serologic test is not FDA approved and because the cost of analyzing a single specimen is prohibitive, state health department partners should not expect that results will be available in real time and should not use the results for clinical purposes. States requesting this service should submit sera to the Foodborne and Diarrheal Diseases immunology laboratory.

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VI. DATA USAGE

FoodNet data belong to individual sites that submit these data. You may use these data as you choose and you are encouraged to use these data to provide feedback to the clinical laboratories, physicians, and other relevant persons within your site.

If you would like to use FoodNet data from more than one site or you would like a CDC author on your site-specific abstract/manuscript, you must follow the Foodborne Diseases Active Surveillance Network (FoodNet) Data Use Policy (Appendix XVI) and the Foodborne Diseases Active Surveillance Network (FoodNet) Protocol Development and Publication Policy (Appendix XVII).

K. LEADERSHIP AND PARTICIPATION

Since FoodNet is a collaborative effort, it is important to have participation and leadership from all those involved, including the state partners. Leadership and participation in FoodNet are measured in several ways. First, each month the FoodNet Steering Committee, including CDC, USDA, FDA and state partners, has a conference call that serves to update all stakeholders on recent FoodNet activities. On these calls, the Steering Committee discusses, among other items, any administrative issues, special studies (e.g., case-control studies), votes on potential proposals for sharing/analyzing the

data, etc. Each FoodNet site should have at least one representative on the Steering Committee call.

Second, leadership and participation in the FoodNet Working Groups is encouraged. The Working Groups are established at the annual Vision Meeting and focus on the priorities set by the Steering Committee. Finally, each site is encouraged to annually submit at least one FoodNet abstract to a national meeting.

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Appendix I: Foodborne Diseases Active Surveillance Network (FoodNet) Case Report Bacterial Form

PHLIS ID Number_____-_____-_____-_____

Local Case ID (Medical Record #): _____ **Isolated Bacteria** _____

Patient's name:_____
Last First

Address_____ **Phone No**: ( ) _____ - _____
Number/ Street City State ZIP

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PHLIS ID # (Patient-Specimen): ❑❑❑❑ ❑❑❑❑~❑❑❑❑❑❑❑❑❑~❑❑❑~❑❑

Local ID _____ ~ ❑❑❑❑

1) COUNTY (residence of patient):

_____

_____

2) SEX:

❒ Male ❒ Female ❒ Unknown

3) DATE OF BIRTH:

_____ /_____ /_____
month day year

4) RACE : (original categories)

❒ **White**

❒ **Black**

❒ **American Indian/ Native Alaskan**

❒ **Unknown**

❒ **Asian or Pacific Islander**

4a) RACE : (additional FN categories)

❒ Asian

❒ Pacific Islander or Native Hawaiian

❒ Multi-racial

❒ Other

5) ETHNICITY:

❒ Hispanic

❒ Non-Hispanic

❒ Unknown

6) SPECIMEN COLLECTION DATE

_____/_____/ 200____
month day

7) AGE:_____
years

8) IF < 1 YEAR, AGE: _____
months

9) SUBMITTING LAB:

_____

_____
Laboratory

9a) SUBMITTING PHYSICIAN:

_____

Phone: ( ) _____ -_____

Informant _____ **Date Report Received in Lab** _____/_____/ 200____
month day

10) SOURCE OF SPECIMEN: ❒ Stool ❒ Blood ❒ CSF ❒ Urine ❒ Unknown ❒ Other site (specify):_____

11) ISOLATED BACTERIA:

❒ ***Salmonella*** (serogroup_____) serotype_____)

❒ ***Shigella*** (serogtype/species_____)

❒ ***Campylobacter*** (species_____)

❒ ***E. coli***

Biochemically identified? Yes ❒ No ❒ Unknown

O157 positive? ❒ Yes ❒ No ❒ Unsure/Not Tested

O antigen number _____

H7 positive? ❒ Yes ❒ No ❒ Unsure/Not Tested

H Antigen Number _____

Isolate non-motile? ❒ Yes ❒ No ❒ Unsure/Not Tested

Shiga toxin-positive? ❒ Yes ❒ No ❒ Unsure/Not Tested

National database PFGE Pattern _____

❒ ***Vibrio*** (species_____)

❒ ***Yersinia*** (species_____)

❒ ***Listeria monocytogenes*** (serotype_____)

Pregnant? ❒ Yes ❒ No ❒ Unknown

Outcome of Fetus?

❒ Abortion/stillbirth

❒ Induced abortion

❒ Live birth/neonatal death

❒ Survived-clinical infection

❒ Survived-no apparent illness

❒ Unknown

❒ Other Bacteria (specify:)_____

Appendix I: Foodborne Diseases Active Surveillance Network (FoodNet) Case Report Bacterial Form

Data Entry: ☐ PHLIS
☐ CASE-CONTROL STUDY
☐ EPI INFO

A. Hospital Follow-up:

13) PATIENT STATUS AT THE TIME OF SPECIMEN COLLECTION:

❒ Hospitalized (*go to 15*) ❒ Unknown (*go to 15c*)

❒ Outpatient (*go to 14*)

---

14) IF OUTPATIENT, WAS THE PATIENT SUBSEQUENTLY HOSPITALIZED?

❒ Yes (*go to15*) ❒ No (*go to 15c*) ❒ Unknown (*go to 15c*)

---

16) OUTCOME: ❒ Alive ❒ Dead ❒ Unknown

16a) HOW WAS THIS INFORMATION (from #16) DETERMINED?

Patient / relative contacted

Physician contacted or chart review / medical records review

Did not follow up

County provided information

B. Health Department Follow-up:

If the isolate was further characterized by the State Lab, please update #11.

17) DID THE STATE LAB RECEIVE THE ISOLATE?

❒ Yes ❒ No ❒ Unknown

17a) If Yes, STATE LAB ISOLATE ID NUMBER:

_____

---

19) WAS CASE FOUND DURING AN AUDIT?

❒ Yes ❒ No ❒ Unknown

---

20) WAS THE CASE PART OF AN OUTBREAK?

❒ Yes (go to 20a) ❒ No ❒ Unknown

20a) IF OUTBREAK RELATED, WAS IT A FOODBORNE OUTBREAK?

Yes(go to 20b) ❒ No ❒ Unknown

20b) EFORS NUMBER: _____

---

15) IF PATIENT WAS HOSPITALIZED (that is, if answered "Hospitalized" to #13 or "Yes" to #14):

Hospital name:_____

Date of admission: _____ /_____ / 200___
month day

Date of discharge: _____ /_____ / 200___
month day

15a) TRANSFERRED TO ANOTHER HOSPITAL?

❒ Yes ❒ No ❒ Unknown

15b) If Yes, TRANSFER HOSPITAL NAME:

_____

15c) HOW WAS THE INFORMATION (from #13,14, or 15) DETERMINED?

❒ Patient / relative contacted

❒ Physician contacted or chart review / medical records review

Did not follow up

County provided information

---

18) DID THE PATIENT TRAVEL WITHIN THE LAST

- **30 days if infected with S. Typhi or Listeria**
- **7 days if infected with other bacterial pathogen**

Yes (go to 17a) No (go to 18) Unknown (go to 18)

18a)
Date of departure from the U.S. : _____ /_____ / 200___
month day

Date of return to the U.S. : _____ /_____ / 200___
month day

---

21) WAS CASE ENROLLED IN THE CASE-CONTROL STUDY? ❒

Yes ❒ No ❒ Unknown

If No, Reason: _____

Reason Code: _____

---

22) IS CASE REPORT COMPLETE? ❒ Yes ❒ No

22a) If Yes, DATE CASE REPORT COMPLETED:

_____ /_____ / 200____
month day

22b) INITIALS OF PERSON COMPLETING CASE REPORT: _____

Comments _____

_____

_____

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Appendix II: Foodborne Diseases Active Surveillance Network (FoodNet) Case Report Parasitic Form

PHLIS ID Number_____-_____-_____-_____

Local Case ID (Medical Record #): _____ **Isolated Parasite** _____

Patient's name:_____
Last First

Address_____ **Phone No**: ( ) _____ - _____
Number/ Street City State ZIP

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PHLIS ID # (Patient-Specimen): ❑❑❑❑ ❑❑❑❑~❑❑❑❑❑❑❑❑❑~❑❑❑~❑❑

Local ID _____ ~ ❑❑❑❑

1) COUNTY (residence of patient):

_____

_____

2) SEX:

❒ Male ❒ Female ❒ Unknown

3) DATE OF BIRTH:

_____ /_____ /_____
month day year

4) RACE : (original categories)

❒ **White**

❒ **Black**

❒ **American Indian/ Native Alaskan**

❒ **Unknown**

❒ **Asian or Pacific Islander**

4a) RACE : (additional FN categories)

❒ Asian

❒ Pacific Islander or Native Hawaiian

❒ Multi-racial

❒ Other

5) ETHNICITY:

❒ Hispanic

❒ Non-Hispanic

❒ Unknown

6) SPECIMEN COLLECTION DATE

_____/_____/ 200____
month day

7) AGE:_____
years

8) IF < 1 YEAR, AGE: _____
months

9) SUBMITTING LAB:

_____

_____
Laboratory

9a) SUBMITTING PHYSICIAN:

_____

Phone: ( ) _____ -_____

Informant _____ **Date Report Received in Lab** _____/_____/ 200____
month day

10) SOURCE OF SPECIMEN: ❒ Stool ❒ GI Aspirate ❒ Small Bowel Biopsy ❒ Unknown ❒ Other site (specify):_____

11) ISOLATED PARASITIC ORGANISM:

❒ ***Cryptosporidium***

How identified? (Please check all that apply):

- ❒ Wet mount, not stained
- ❒ Wet mount, temporary stain, type: _____
- ❒ Acid fast, type: _____
- ❒ FA (Direct immunofluorescence)
- ❒ ELISA, specify immunoassay method:_____
- ❒ PCR
- ❒ Other, please specify:_____

❒ ***Cyclospora***

How identified? (Please check all that apply):

- ❒ Wet mount, not stained
- ❒ Wet mount, temporary stain, type: _____
- ❒ Wet mount, autofluorescence
- ❒ Acid fast, type: _____
- ❒ Safranin, type: _____
- ❒ PCR
- ❒ Other, please specify:_____

Appendix II: Foodborne Diseases Active Surveillance Network (FoodNet) Case Report Parasitic Form

Data Entry: ☐ PHLIS
☐ CASE-CONTROL STUDY
☐ EPI INFO

A. Hospital Follow-up:

13) PATIENT STATUS AT THE TIME OF SPECIMEN COLLECTION:

❒ Hospitalized (*go to 15*) ❒ Unknown (*go to 15c*)

❒ Outpatient (*go to 14*)

13a) OISD (Other immunosuppressive diseases):

❒ Yes ❒ No ❒ Not available

14) IF OUTPATIENT, WAS THE PATIENT SUBSEQUENTLY HOSPITALIZED?

❒ Yes (*go to15*) ❒ No (*go to 15c*) ❒ Unknown (*go to 15c*)

16) OUTCOME: ❒ Alive ❒ Dead ❒ Unknown

16a) HOW WAS THIS INFORMATION (from #16) DETERMINED?

Patient / relative contacted

Physician contacted or chart review / medical records review

❒Did not follow up

❒ County provided information

B. Health Department Follow-up:

If the isolate was further characterized by the State Lab, please update #11.

17) DID THE STATE LAB RECEIVE THE ISOLATE?

❒ Yes ❒ No ❒ Unknown

17a) If Yes, STATE LAB ISOLATE ID NUMBER:

_____

20) WAS THE CASE PART OF AN OUTBREAK?

❒ Yes(go to 20a) ❒ No ❒ Unknown

20a) IF OUTBREAK RELATED, WAS IT A FOODBORNE OUTBREAK?

Yes(go to 20b) ❒ No ❒ Unknown

20b) EFORS NUMBER: _____

22) WAS CASE ENROLLED IN THE CASE-CONTROL STUDY?

❒ Yes ❒ No ❒ Unknown

If No, Reason: _____

Reason Code: _____

15) IF PATIENT WAS HOSPITALIZED
(that is, if answered "Hospitalized" to #13 or "Yes" to #14):

Hospital name:_____

Date of admission: _____ /_____ / 200___
month day

Date of discharge: _____ /_____ / 200___
month day

15a) TRANSFERRED TO ANOTHER HOSPITAL?

❒ Yes ❒ No ❒ Unknown

15b) If Yes, TRANSFER HOSPITAL NAME:

_____

15c) HOW WAS THE INFORMATION (from #13,14, or 15) DETERMINED?

❒ Patient / relative contacted

❒ Physician contacted or chart review / medical records review

Did not follow up

❒ County provided information

18) DID THE PATIENT TRAVEL WITHIN THE LAST 15 DAYS?

Yes (go to 17a) No Unknown

18a)

Date of departure from the U.S. : _____ /_____ / 200___
month day

Date of return to the U.S. : _____ /_____ / 200___
month day

19) WAS CASE FOUND DURING AN AUDIT?

❒ Yes ❒ No ❒ Unknown

21) IF AVAILABLE, PLEASE INDICATE:

Date of illness onset: ____ /_____ / 200___ ❒ Not Available
month day

Date of diarrhea onset: ____ /_____ / 200__ ❒ Not Available
month day

23) IS CASE REPORT COMPLETE? ❒ Yes ❒ No

23a) If Yes, DATE CASE REPORT COMPLETED:

_____ /_____ / 200____
month day

23b) INITIALS OF PERSON COMPLETING CASE REPORT: _____

Comments _____

Revised January 22, 2002

Appendix III: Foodborne Diseases Active Surveillance Network (FoodNet) Variable Definitions

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The variables listed are from the Case Report Form, which is a hard copy based on the Public Health Laboratory Information System (PHLIS) Foodborne Illness Module. Numbered variables on the Case Report Form are included in the PHLIS Foodborne Illness Module. Unnumbered variables are provided at site request to help track patients and specimens.

PHLIS ID Number: During data entry, the PHLIS program automatically assigns the id number. The first eight digits correspond to the site ID,[SITE_ID], the next 9 digits are the patient ID, [PAT_ID] and the next three are the specimen ID. The specimen ID distinguishes between multiple specimens for a case, i.e. from different sources or different days. The last 2 digits are the aliquot ID which is used when a single specimen is split for multiple tests. PHLIS will permit multiple specimens per patient through the structure of its relational database. Information on the algorithm to be used with multiple samples per patient is provided in the Case Ascertainment Instructions.

Local Case ID: [LOCAL_ID] Case medical record number

[SNAPDATE]: Date PHLIS data was uploaded to Foodnet for each site

Patient name, address, and phone number: Personal identifiers will be entered into the database but will be encrypted during data transmission to the CDC. City, [CITY] State, [STATE] and ZIP code [ZIPCODE] will be transferred to CDC unencrypted. Data at lower sites, such as Grady Hospital in Atlanta or the Oakland Office in California, will be unencrypted when received in the higher site.

County [COUNTY]: This records the patient's county of residence. This will be used to determine whether or not the individual resides within the catchment area and therefore whether the individual will be included in the data.

> *Protocol for homeless cases: Enter 'homeless' in the address field, '99999' as the zipcode, leave the city field blank, and enter the appropriate county from where the case was reported.*

Sex [SEX]: Male, Female, or Unknown

Date of Birth [DOB]: Month/Day/Year

Race [RACE]: If known (white, black, American Indian/Native Alaskan, Asian/Pacific Islander) or unknown.

Race-additional census categories: This is a new question for 2002 to capture more specific data on race. The pick list includes **Asian, Pacific Islander/Native Hawaiian, Multi-racial, and Other**. These additional choices have been added as part of FoodNet to all isolate modules for compliance with the new census categories. This question will be skipped if the answer to "Race" is White, Black, American Indian/Native Alaskan, or Unknown. Otherwise you will be prompted to fill in this variable.

Ethnicity [ETHNICITY]: If known (Hispanic, Non-Hispanic, unknown)

Specimen date [SPECDATE]: Month/Day/Year of specimen collection. If this information is unavailable, please provide "Date received in laboratory" in the appropriate field [DT_RCVD].

Age/Age in months [AGE_YR, AGE_MNTH, AGE_DAYS]: PHLIS will calculate this information, given the "Date of Birth" and the "Specimen date". This age is in years. If the patient is less than one year old, age in months is used. If the patient is less than 1 month old, age in days in used.

Submitting Lab/Phone: This list of hospital and reference labs will be in picklist format in the module. **The module does not have the picklist installed for each site.** The picklist is created by the user during data entry. In the PHLIS module, at the variable "Submitting lab", hit the insert key to add to the picklist and type the name of the hospital or reference lab. The phone number will not be entered into PHLIS. [SUBLAMNM]

Submitting Physician/Phone/ Address: This information is not transmitted to the CDC but was requested by the sites in order to follow up isolates sent to reference labs.

Source of Specimen [SPECSRCE]: Site from which specimen was collected, including stool, urine, blood, CSF, or other sterile site such as bones or joints.

Revised January 22, 2002

Appendix III: Foodborne Diseases Active Surveillance Network (FoodNet) Variable Definitions

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- Isolated Bacteria and Confirmed Parasites [ISOLATE]: The list of bacteria includes *Salmonella, Shigella, Campylobacter, E. coli* (STEC)*, Vibrio, Listeria monocytogenes, and Yersinia enterocolitica*. The list of parasites include Cryptosporidium and Cyclospora.
- Once the bacteria is selected, a second picklist of serotype, if known, is provided for: [SEROTYPE]
- Shigella: [SHIGSERO]
- Campylobacter: [CAMPSPEC]
- Yersinia
- Vibrio: [VIBROSPC]
- Listeria: [LISTSERO]
- Additional variables on Salmonella serogroup and serotype are also provided: [SAL_GRP, SAL_SERO]
- If the bacterial pathogen is *E. coli* (STEC) or *Listeria*, additional information is requested:

E.coli / STEC

Biochemically identified as E. coli? [BIOID] Yes, No, Unsure/not tested, Unknown
O157positive? [O157POS] Yes, No, Unsure/not tested, Unknown
O antigen number [OANTIGNO] ###
H7 Antigen Positive?: [HANTPOS] If final identification is *E. coli* O157, was it H 7 antigen positive? Yes, No, Unsure/not tested
H Antigen Number [ECOLANT]: If H antigen positive, provide H antigen number ##.
Isolate non-motile? [NONMOTIL] Yes, No, Unsure/not tested
Shiga toxin Positive: [SHIGTPOS] If *E. coli* is Nonmotile, was it Shiga-like toxin producing? Yes, No, Unsure/Not tested

Listeria

Pregnant? [PREGNANT] Yes, No, Unknown
Outcome of Fetus? [FOUTCOME] Abortion/stillbirth, Induced abortion, Live birth/neonatal death, Survived-clinical infection, survived -no apparent illness, unknown

Specimen ID number (accession #): This information is **not transmitted** to the CDC but was requested by the sites to track specimens by the accession number from the lab sample.

Date received in laboratory: This information is required only if the Specimen Collection Date is unavailable. Month, Day, and Year the specimen was received in the laboratory. [DT_RCVD]

* Patient Status at time of specimen collection [PSTATCOL]: Was the patient an inpatient, an outpatient, or unknown. An ER collection is counted as an outpatient. For ER discharges with no follow-up, 'subsequent hospitalization' and 'outcome' will be coded as 'unknown'.

If outpatient, was patient subsequently hospitalized [OPATHOSP]: Outpatients who are hospitalized within 7 days of specimen collection, should be counted as 'yes'. If we cannot find out if case was subsequently hospitalized, make no assumptions and enter 'unknown'.

If hospitalized, please provide the following information:
Hospital name [HOSPNAME], Date of admission [HDTOFADM], Date of discharge [HDTOFDIS], if transferred to another hospital [XFR2OHOS], and the name of the hospital to which the patient was transferred [XFRHOSNM]. Patient ID number is the medical record number or chart number of the hospitalized patient. This variable is not included in the PHLIS module because it is a patient identifier. It is included on the Case Report Form in order to follow up the hospitalized patients. A picklist can be created for the "Hospital name" in the same way as for "Submitting lab".

How was the information determined? [HINFODET]: How information from questions 13, 14, or 15 were determined. Choices are patient or relative contacted, physician contacted or chart review/medical records review, did not follow up, or county provided information

Appendix III: Foodborne Diseases Active Surveillance Network (FoodNet) Variable Definitions

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Outcome [OUTCOME]: Alive, Dead, Unknown. If outpatient, death within 7 days of culture confirmation date, if hospitalized, follow-up until patient is discharged or dies. If hospitalization is <7 days, data from hospital discharge will still be used for 'outcome'.

How was the information determined? [OINFODET]: How information from question 16 was determined. Choices are patient or relative contacted, physician contacted or chart review/medical records review, did not follow up, or county provided information

Did the state receive the isolate?: [STLABRIS] Did the hospital or reference lab forward the isolate, yes, no, or unknown?

* If yes, isolate number: [SLABSID] Each state lab should assign a unique isolate ID number. This isolate ID number will be used to link isolates forwarded to CDC by state health departments for anti-microbial testing.

Case found during an audit? Yes, no, or unknown

Case in case-control study? [CASE_IN] Yes, no, or unknown (Only for cases of pathogens for which we are conducting an ongoing case control study.)

If no, reason case is not enrolled in case control study [REASON]: Only for cases of pathogens for which we are conducting an ongoing case control study. If surveillance case was not enrolled as a case in the case control study, reason why excluded. Choices may vary by study, but will usually include: not reachable after 15 calls, do not have home phone, non English speaker, unable to answer questions, did not have diarrhea, no onset of diarrhea, diarrhea onset > 10 days before collection, outbreak associated, unable to interview within 21 days of collection, refused, not in catchment area, immunocompromised, not selected in random sample, chronic carrier, family member with positive culture/bloody diarrhea, unable to contact patient, outside of study time period, no control was found, or other reason.

Is case report complete? [CASRPTC] Yes, no, or unknown: CDC can track the number of completed forms with this variable. A case report form will be complete if all known variables are provided.

* Complete, Date, Initials [CASRPTCD, CASRPTCI]: When the case report form is complete, the person completing the form should initial and date the form. No may be entered in the PHLIS module, but this information will be updated to yes once the form is complete or all information available is collected

* Must enter data into PHLIS module

Appendix IV: Documentation of FoodNet Variables

PHLIS Variable's Name	PHLIS Variable's Data Type	PHLIS Variable's Data Length	FoodNet Variable's Data Type	Variable Description	Potential Answers
RES1XHX	Character	1	Character	race- additional categories	A [Asian], M [Multi-Racial], O [Other], P [Pacific Islander or Native American]
AGE_MO	Character	2	Numeric	age of patient in months if patient is less than 1 year old	
AGE_YRS	Character	3	Numeric	age of patient in years	
ALIQUOT_ID	Character	2	Character	aliquot id	
RES1X1R	Character	10	Character	was the ecoli biochemically identified as *E.coli*	No, Not Tested, Unknown, Yes
RES1DDF	Character	15	Character	*Campylobacter* species	*bubulus, coli, cryaerophilia, doylei, fetus,*
RES1XAP	Character	1	Character	case in case-control study?	No, Unknown, Yes
RES1X47	Character	7	Character	is case report complete?	No, Yes
RES1X48	Date	YYMMDD8.	Date	date case report form was completed	
RES1X49	Character	3	Character	initials of person completing case report form	
CITY	Character	15	Character	city	
COUNTY	Character	20	Character	county of residence	* see census document
BIRTHDATE	Date	YYMMDD8.	Date	date of birth	
RES1X1B	Date	YYMMDD8.	Date	date specimen received in laboratory (only if specimen collection date unavailable)	
RES1X1Q	Character	2	Character	what is the H antigen number?	1-999
			Numeric	EFORS outbreak number	1-999999
ENTRY_DATE	Date	YYMMDD8.	Date	date entered	
ETHNIC	Character	1	Character	ethnicity	H (Hispanic), N (Non-Hispanic), U (Unknown)
RES1XFA	Character	3	Character	outcome of fetus?	1 (Survived, no apparent illness)
					2 (Survived, clinical infection)
FIRST_NAME	Character	12	Character	patient's first name, encrypted when arrives at cdc	should be blank or encrypted
RES1DEA	Character	20	Character	If O157, was it H7 antigen positive?	No, Unsure/Not Tested, Yes
RES1X3L	Date	YYMMDD8.	Date	date of hospital admission	
RES1X3M	Date	YYMMDD8.	Date	date of hospital discharge	

Appendix IV: Documentation of FoodNet Variables

PHLIS Variable's Name	PHLIS Variable's Data Type	PHLIS Variable's Data Length	FoodNet Variable's Data Type	Variable Description	Potential Answers
RES1XH4	Character	55	Character	how hospital information was obtained?	County provided information, Did not follow-up, Patient or relative contacted, Physician contacted or chart/medical records/death cert
RES1X3J	Character	30	Character	Hospital name	
RES1XHY	Character	7	Character	Is the case international travel related?	Yes, No, Unknown
DISEASE_D	Character	15	Character	name of pathogen isolated	*Campylobacter* , *E. coli* 0157, *Cryptosporidium* , *Cyclospora* , *Listeria* , *Salmonella* , *Vibrio* , *Yersinia* , *Shigella* , STEC O Ag Undet , STEC Non O157
LAB_NUMBER	Character	12	Character	local aliquot ID	
LAST_NAME	Character	25	Character	patient's last name, encrypted when arrives at cdc	should be blank or encrypted
RES1XH9	Character	10	Character	*Listeria* serotype	1/2A, 1/2B, 1/2C, 3A, 3B, 3C, 4B, Unknown, Untypeable
LOCAL_ID	Character	16	Character	case medical record number	
RES1X1N	Character	7	Character	was the isolate non-motile?	No, Unknown, Yes
RES1DE9	Character	20	Character	was the ecoli O157 positive?	No, Unsure/Not Tested, Yes
RES1X1P	Character	3	Numeric	what is the O antigen number?	1-999
RES1XH5	Character	60	Character	how outcome information was obtained?	County provided information, Did not follow-up, Patient or relative contacted, Physician contacted or chart/medical records/death cert
RES1X3I	Character	7	Character	if outpatient, was patient subsequently hospitalized?	No, Unknown, Yes
RES1DDH	Character	7	Character	outbreak related?	No, Unknown, Yes
RES1WYH	Character	7	Character	outcome of patient	Alive, Dead, Unknown
PATIENT_ID	Character	9	Character	patient id number generated by phlis	
RES1XFB	Character	3	Numeric	If listeria isolate, was patient pregnant?	1 (Yes), 2 (No)
RES1X3H	Character	12	Character	patient status at time of collection	Hospitalized, Outpatient, Unknown
RACE	Character	1	Character	race	I-Native American
RES1X4B	Character	2	Character	*Salmonella* serogroup	
RES1764	Character	60	Character	*Salmonella* serotype	
GENDER	Character	1	Character	sex	M (male), F (female), U (unknown)
RES1DDW	Character	60	Character	*Shigella* species	*boydii, dysenteriae, flexneri, sonnei, unknown*

Appendix IV: Documentation of FoodNet Variables

PHLIS Variable's Name	PHLIS Variable's Data Type	PHLIS Variable's Data Length	FoodNet Variable's Data Type	Variable Description	Potential Answers
RES1X1O	Character	10	Character	If *E. coli* , was it shiga-like toxin producing?	No, Not Tested, Unknown, Yes
SITE_ID	Character	10	Character	site id number generated by phlis automatically (location/number of computer where data was entered)	** (see table at bottom)
RES1X3R	Character	30	Character	state lab id	^ see FN/NARMS linking table for correct format (should be unique for each case)
SPEC_ID	Character	3	Character	specimen id number generated by phlis	
DATE_TAKEN	Date	YYMMDD8.	Date	specimen collection date	
SOURCE	Character	60	Character	site from which specimen was collected	Abscess, Blood, CSF, Other, Stool, Unknown, Urine
STATE	Character	2	Character	state	CA, CO, CT, GA, MD, MN, NM, NY, OR, TN
RES1XAD	Character	7	Character	did the hospital or reference lab forward the isolate?	No, Unknown, Yes
LAB_NAME	Character	25	Character	name of submitting laboratory	
RES1XGI1	Memo	350	Memo	Underlying causes or associated illness	AIDS, Alcohol Abuse, Artherosclerotic Cardiovascular Disease (ASCVD/CAD), Asthma, Blunt Trauma, Burns, Cirrhosis, CSF Leak (2 trauma/surgery), Diabetes Mellitus, Emphysema/COPD, Heart Failure/CHF, HIV Infection, Hodgkin's Disease, Immunoglobulin Deficiency, Immunosuppressice Therapy (steriods, chemotherapy, radiation), IVDU, Leukemia, Multiple Myeloma, Nephrotic Syndrome, Organ Transplant, Other Illness, Other Malignancy, Penetrating Trauma, Renal Failure/Dialysis, Sickle Cell Anemia, Splenectomy/asplenia, Surgical Wound (post operative), Systemic Lupus Erythematosus (SLE), Unknown, Varicella

Appendix IV: Documentation of FoodNet Variables

PHLIS Variable's Name	PHLIS Variable's Data Type	PHLIS Variable's Data Length	FoodNet Variable's Data Type	Variable Description	Potential Answers
RES1XAQ	Character	2	Character	reason not in case-control study?	01 [Non-English/non-Spnaish speaker], 10 [No surrogate available], 11 [Unable to answer questions], 12 [Physician did not allow patient contact/physician refused], 02 [Case refused], 03 [Case not reachable after 15 calls], 04 [Do not have home phone], 05 [Outbreak associated], 06 [Unable to interview within 30 days of collection due to laboratory issues], 07 [Unable to interview within 30 days of collection due to county health], 08 [Unable to interview within 30 days of collection due to other], 09 [Not in catchment area]
RES1XHZ	Date	YYMMDD8.	Date	Date of departing from U.S.	
RES1XI0	Date	YYMMDD8.	Date	Date of returning to U.S.	
RES1X7P	Character	24	Character	*Vibrio* species	*alginolyticus, cholerae, cincinnatiensis, damsela, fluvialis hollisae, mimicus, parahaemolyticus, vulnificus, uknown*
RES1X3N	Character	7	Character	transferred to another hospital?	No, Unknown, Yes
RES1X3O	Character	30	Character	name of transfer hospital	
RES1XFC	Character	24	Character	*Yersinia* species	*aldovae, bercovieri, enterocolitica, frederiksenii, intermedia, kristensenii, mollaretii, pestis, philomiragia, pseudotuberculosis, rohdei, ruckeri*
ZIP	Character	9	Character	zipcode	

Appendix V: FoodNet/NARMS Performance Standards, 2003

Surveillance

1. Case follow-up

    a. Percent of cases with "unknown" hospitalization
    (hospitalization within 7 days of culture collection date)
    Target: <= 50% unknown

    b. Percent of **outpatient/ER cases** with "unknown" outcome
    (If outpatient, death within 7 days of culture collection date; if hospitalized, follow-up until patient is discharged or dies)
    Note: See attached sheet for additional information.
    Target <= 50% unknown

    c. Percent of **hospitalized cases** with "unknown" outcome
    Target <=15% unknown

2. Timeliness - median days from culture collection to data entry in PHLIS/state system (In MD, NY, CO, and GA, a variable will be added into PHLIS to allow monitoring of this standard.)
Target: <= 15 days

3. HUS surveillance - measure of participation
Target: Report to CDC at least once per month

4. Outbreak surveillance - measure of participation
Target: Summary report to CDC at least once per month
Target: Report 85% of outbreaks to CDC within 2 weeks of 'Date first case became ill'
FoodNet will determine method for measuring this standard.
Target: Finalize 70% of reports within 2 months of first onset
Coordinators proposed to revise because current standard is not measurable.

NARMS

5. Isolate submission - percent of cases which should have had an isolate submitted, that did have an isolate submitted, 2 month lag time allowed

Target: Every 20th non-Typhi *Salmonella* in surveillance
Every 20th *E. coli* O157 in surveillance
1 *Campylobacter* isolate per week
Every 20th *Shigella* in surveillance
All *Salmonella* Typhi in surveillance
All *Listeria monocytogenes* in surveillance
All *Vibrio* in surveillance

Appendix V: FoodNet/NARMS Performance Standards, 2003

PulseNet

6. PFGE testing - percent of cases which should have had a PFGE pattern submitted, that did have a PFGE pattern submitted

Target: All *E. coli* O157, *Salmonella* Typhimurium, and *Listeria monocytogenes* in surveillance

FoodNet will add a timeliness factor to this standard once a method for measuring it is established.

7. Isolates received at state laboratory from clinical labs

a. Target: >= 85% *E. coli* O157 in surveillance
Target: >= 85% *Salmonella* in surveillance
Target: >= 95% *Listeria monocytogenes* in surveillance
Target: >= 90% *Vibrio* in surveillance

b. Target >= 95% of bacterial isolates (except *Campylobacter*) will have serotype/species information entered into the FoodNet system

Case-control studies

8. Percent of cases eligible for case-control studies which were enrolled

Target: >= 50% enrollment of eligible cases in surveillance
("eligible" as defined in methods for each study)

a. Percent of cases enrolled in *Listeria* case-control study
Target: >= 85% of cases enrolled with >=2 controls

b. Percent of cases enrolled in *cryptosporidium* case-control study (for sites participating in *Cryptosporidium* case-control study)
Target: >= 85% of cases enrolled with 2 controls

Leadership

9. Participation

a. Percent of Steering Committee conference call with site representative
Goal: Representatives from each site should attend 100% of calls

b. Percent of Data-Sharing conference call with site representative
Goal: Representatives from each site should attend >= 5 of 6 (83%) calls per year

10. Number of 1st authored abstracts submitted yearly to national meetings

Goal: Each site should submit >= 1 FoodNet abstract (site specific or aggregated data) per year to a national meeting

11. **Target of 100% of Vibrios reported through FoodNet surveillance will be reported to FDDB on appropriate surveillance form in timely fashion. ("timely fashion" still to be determined)**

12. **Target of __ % of Vibrio isolates received at state lab will be sent to CDC.**

13. **Target of capturing *Listeria* serotype information in FoodNet database in timely fashion so as to be useful for sites (for example in identifying clusters). ("timely fashion" still to be determined)**

14. **Target of 100% completion of 'State Lab ID' variable in FoodNet surveillance for isolates submitted to NARMS and PulseNet.**

Appendix V: FoodNet/NARMS Performance Standards, 2003

ADDITIONAL INFORMATION FOR PERFORMANCE STANDARD #1

1.) Hospitalization for any reason during the 7 day window will be recorded as a 'yes'.
(If >7 day window is used, CDC FoodNet can subset data to include only those with 7 day window.)

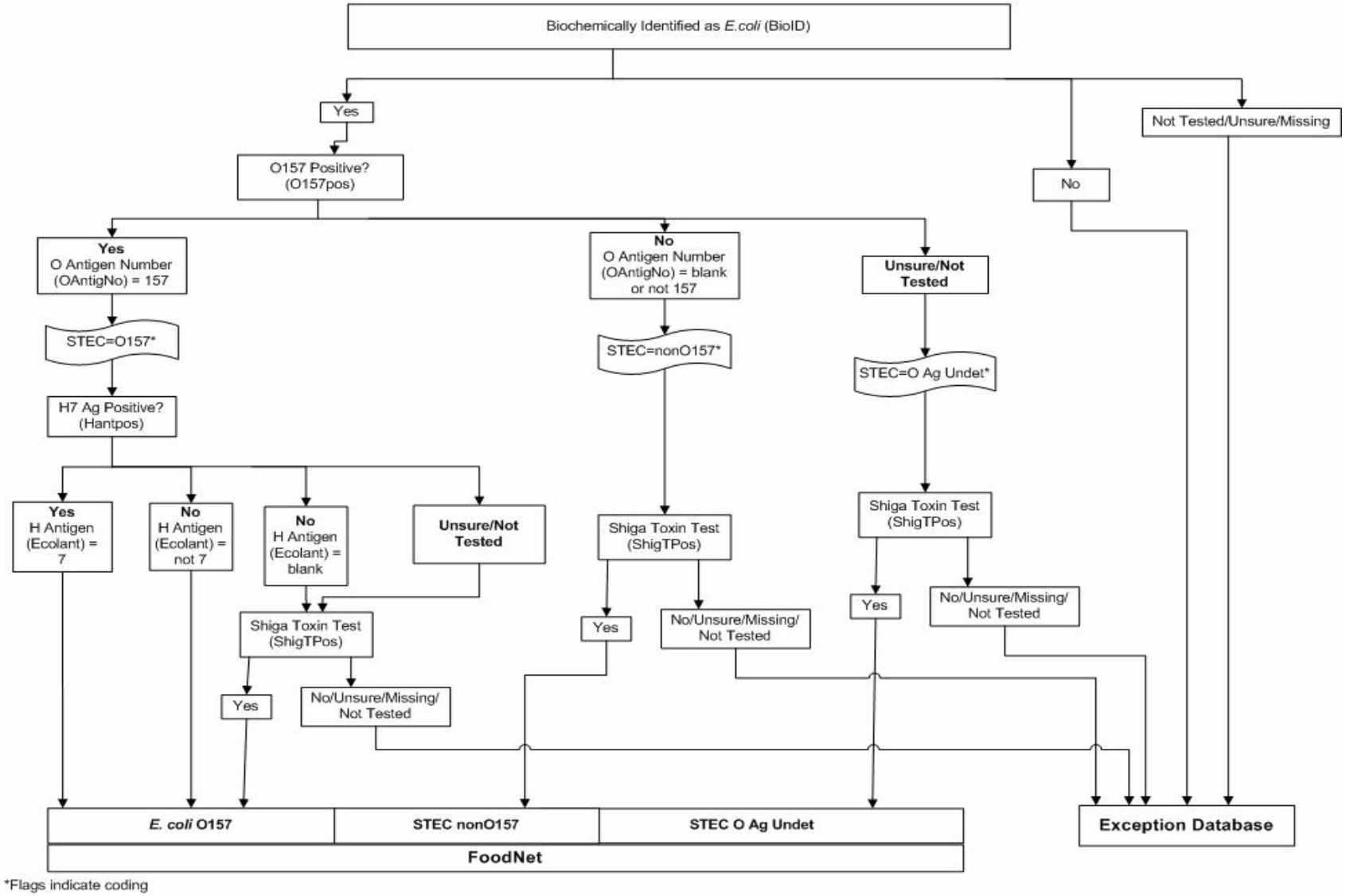
2.) If hospitalization is <7 days, data from hospital discharge will still be used for 'outcome'.

3.) ER visits are considered 'outpatient'. For ER discharges with no follow-up, 'subsequent hospitalization' and 'outcome' will be coded as 'unknown'.

4.) ER Chart requests that are not fulfilled will be coded as 'unknown'.

5.) FoodNet Case report form will be modified to reflect changes.

Appendix VI: FoodNet Criteria for Classification of Shiga toxin-producing *E. coli* (STEC)



*Flags indicate coding

Appendix VII: *Listeria* Case Form

Draft 2/19/2004

Completed by_____ Date completed_____

Please obtain information from children ≥ one month of age and adults. In the event of a fetal or neonatal (<1 month of age) infection the mother is considered the case-patient and the mother's food consumption history should be collected.

CASE INFORMATION

Patient's name:

Patient's address:

(Street Address) (City) (State) (Zip)

Phone numbers: (h) ( ) (w) ( ) (mobile) ( )

DOB (mm/dd/yyyy): ___/___/___

Ethnicity: (check all that apply)
[ ] Hispanic/Latino
[ ] Non Hispanic/Latino
[ ] Unknown

Race: (check all that apply)
[ ] American Indian/Alaska Native [ ] African American/Black
[ ] Asian [ ] White
[ ] Native Hawaiian/Pacific Islander [ ] Unknown

---------- Please detach at perforation to remove personal identifiers----------

Age: ___ years ___months **Sex:** [ ] M [ ] F [ ] Unknown

State of residence: _____ **PulseNet Pattern Numbers:** *Asc*I:_ GX6A16._____

State (laboratory) ID No _____ *Apa*I:_ GX6A12._____

State Outbreak ID No_____ Other enzyme:_____

CDC ID No _____ **Serotype** ____

CDC Outbreak (EFORS) ID No_____ **Ribotype**_____

PREGNANCY ASSOCIATED CASES AND NEONATAL INFECTIONS (<1 MONTH OF AGE)

PREGNANCY ASSOCIATED CASE? [ ] Yes [ ] No [ ] Unknown.

If NO, skip to 'CASES NOT ASSOCIATED WITH PREGNANCY'.

If yes,

Did the mother have culture-confirmed listeriosis during pregnancy? [ ] Yes [ ] No [ ] Unknown

What type of infection did the pregnant woman have?

[ ] Bacteremia/Sepsis [ ] Meningitis [ ] Febrile gastroenteritis

[ ] Amnionitis [ ] No symptoms [ ] Unknown [ ] Other, specify_____

Type of specimen collected on woman: [ ] Blood [ ] Stool [ ] CSF [ ] None [ ] Other, specify_____

Date specimen collected (mm/dd/yyyy): ___/___/___

What was the outcome of the pregnancy? [ ] Still pregnant [ ] Miscarriage [ ] Stillbirth [ ] Preterm delivery (live birth)

[ ] Term delivery (live birth) [ ] Other, specify_____

Was the mother hospitalized for her listeriosis illness [ ] Yes [ ] No [ ] Unknown

If yes, Date of admission (mm/dd/yyyy) ___/___/___ Date of discharge (mm/dd/yyyy) ___/___/___

Name of Hospital: _____

What was the mother's outcome? [ ] Survived [ ] Died [ ] Unknown

FETAL AND NEONATAL (<1 MONTH OF AGE) INFECTIONS

Did the fetus or neonate have culture-confirmed listeriosis? [ ] Yes [ ] No [ ] Unknown

If yes,

What type of infection did the child have? [ ] Meningitis [ ] Bacteremia/Sepsis [ ] Granulomatosis infantisepticum

[ ] Unknown [ ] Other, specify_____

Type of specimen collected on child: [ ] Blood [ ] CSF [ ] Placenta [ ] Other, specify_____

Date specimen collected (mm/dd/yyyy): ___/___/___ Child's DOB (mm/dd/yyyy): ___/___/___

Child's Outcome: [ ] Survived [ ] Died [ ] Unknown

CASES NOT ASSOCIATED WITH PREGNANCY

Type of specimen collected: [ ] Blood [ ] Stool [ ] CSF [ ] Other, specify_____

Date specimen collected (mm/dd/yyyy): ___/___/___

Type of infection: [ ] Bacteremia/Sepsis [ ] Meningitis [ ] Febrile gastroenteritis

[ ] Unknown [ ] Other, specify_____

Was patient hospitalized? [ ]Yes [ ] No [ ] Unknown

If yes, Date of admission (mm/dd/yyyy) ___/___/___ Date of discharge (mm/dd/yyyy) ___/___/___

Name of Hospital: _____

Case-patient's Outcome: [ ] Survived [ ] Died [ ] Unknown

Appendix VIII: *Salmonella* serotyping

Salmonella serotyping

Patricia Fields PhD
National *Salmonella* Reference Lab
Foodborne and Diarrheal Diseases Branch
CDC
September 12, 2003

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What is serotyping?

- The "first-generation" subtyping method
- Phenotypic characterization of strains based on the immunologic reactivity of two surface structures:
  - Lipopolysaccharide (O antigen)
  - Flagellin protein (H antigen)
- In *Salmonella*, includes species and subspecies identification
  - Isolates of different subspecies can have the same O and H antigens

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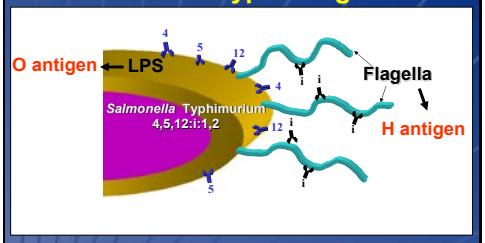
Schematic Representation of *Salmonella* Serotype Antigens



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Salmonella taxonomy

- Two species of *Salmonella*
  - *Salmonella enterica*
  - *Salmonella bongori* (formerly subspecies V)
- *Salmonella enterica* is further divided into 7 subspecies
  - Designated by roman numerals
  - 99% of human isolates are subspecies I
  - Subspecies II, IIIa, IIIb, IV, VI
    - Subspecies IIIa and IIIb used to be genus *Arizonae*
  - Subspecies VII recognized but not used for the purpose of serotype designation
- Species/subspecies typically determined by biochemical testing

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Salmonella enterica subspecies

I	*enterica*
II	*salmonae*
IIIa	*arizonae*
IIIb	*diarizonae*
IV	*houtenae*
VI	*indica*

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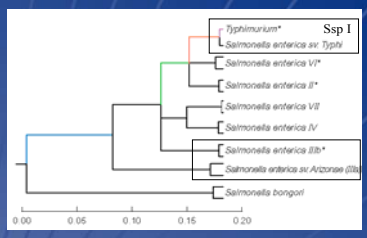
Differentiating *Salmonella* subspecies



*Whittam and Bumbaugh, Curr Opin Gen Dev 12:719-725 (2002)

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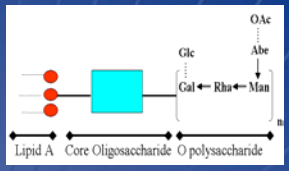
Salmonella O antigen

- Outermost portion of lipopolysaccharide (LPS)



- Carbohydrate antigen
- Different sugars and different linkages between sugars produce the different antigens

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Salmonella O Antigens

- "O Group" antigens are the most important for determining serotype
- 46 O serogroups (encoded by the *rfb* region)
  - O groups initially designated by capital letters
  - Ran out of letters … started using numbers
  - Now, all O Groups are designated by numbers
  - Letter designations still commonly used

O Group (number designation)	O Group (letter designation)
4	B
7	C1
8	C2
9	D1
3,10	E1
13	G

These O groups represent about 97% of human isolates

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Appendix VIII: *Salmonella* serotyping

Salmonella O Antigens (cont)

- 11 additional O antigens that are not encoded by the *rfb* region
  - Found in specific O groups
- Most can be variable within a given serotype, so are less important for serotype determination
- Typically encoded by extra-chromosomal elements
  - One encoded on a plasmid
  - Several encoded by bacteriophages
    - Others likely to be encoded by bacteriophages, too

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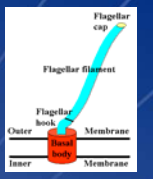
Salmonella H antigen

- Flagellin, the flagellar filament
  - A protein antigen
  - Variation in the middle surface-exposed portion of the protein
- *Salmonella* is unique in having 2 different H antigens:
  - Phase 1
  - Phase 2
  - The 2 flagellin genes are coordinately expressed—one is off when other is on
  - Some serotypes are "monophasic"—have only one flagellar antigen



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Salmonella H Antigens

- 119 H antigens (Phase 1 & Phase 2)
  - Typically designated by lower case letters
    - 1,2; 1,5; 1,7; *et al* are the notable exceptions
  - Ran out of letters … started using numbered z's
    - z_4, z_6, z_{10}, z_{15}, … z_{89}
    - Typically, no antigenic relationships between "z" antigens
- Some H antigens are antigenically related
  - Related antigens referred to as "complexes"
  - Typically, have one antigen in common plus secondary antigens
  - 1 complex, G complex, E complex, EN complex, z_4 complex

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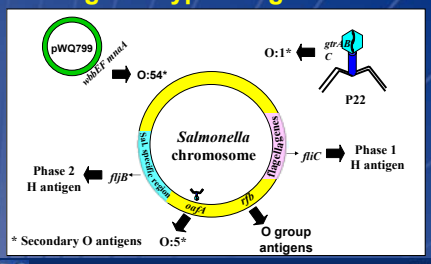
Genomic location of genes encoding serotype antigens



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Subspecies II – VI serotypes are designated by a formula

"Group O:48" or "Group Y"

IV 48 : g,z51 : -*

Subspecies | O antigen | Phase 1 | "monophasic"

* *Salmonella* IV 48:g,z51:- was formerly known as *S.* Marina.

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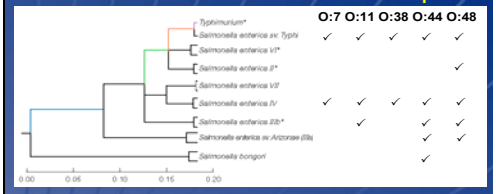
Distribution of *Salmonella* O Groups



- **Subspecies determination is critical for serotype identification, particularly for "higher" O groups**

* Dendrogram taken from Whittam and Bumbaugh, Curr Opin Gen Dev 12:719-725 (2002)

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Designation of *Salmonella* Serotypes

- Designated according to the conventions of the Kauffmann-White Scheme
  - Established 1929
  - 44 serotypes in 1934
    2,523 serotypes in 2001
- Kauffmann-White Scheme maintained by Institut Pasteur
  - Popoff, MY. 2001. Antigenic Formulas of the *Salmonella* Serovars, 8th edition. WHO Collaborating Centre for Reference and Research on *Salmonella*, Pasteur Institute, Paris, France.
    - Published every five years
    - Updated annually

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Subspecies I serotypes are designated by a name or a formula

S. Typhimurium

"Group O:4" or "Group B"

I 1, 4, [5], 12 : i : 1,2

Subspecies | O antigen | Phase 1 | Phase 2 H antigens

I 4,5,12 : i : 1,2
I 1,4,5,12 : i : 1,2
I 4,12 : i : 1,2 } *S.* Typhimurium var. O 5 ⁻ or var. Copenhagen
I 1,4,12 : i : 1,2 }

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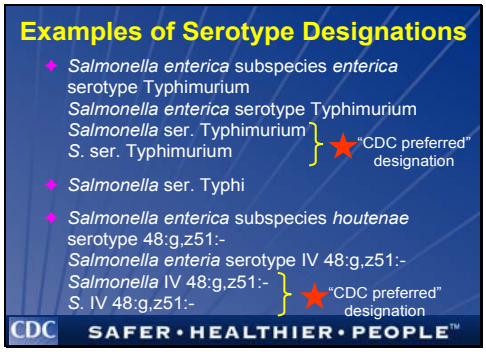
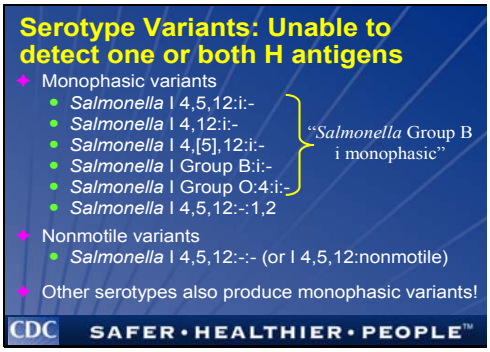
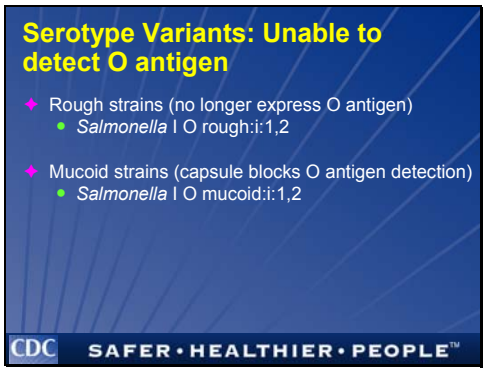
Appendix VIII: *Salmonella* serotyping







Appendix IX: Overview of *Salmonella* Serotype Designation

1) *Salmonella* Taxonomy[1]

The **genus *Salmonella*** divided into two species, *Salmonella enterica* and *Salmonella bongori.*

Salmonella enterica is further subdivided into 6 subspecies that are designated by names or Roman numerals. The Roman numerals are simpler and more commonly used. Subspecies IIIa and IIIb were historically considered a separate genus, ***Arizonae***, and are still sometimes referred to by this name.

***Salmonella enterica* subspecies**	
I	*enterica*
II	*salamae*
IIIa	*arizonae*
IIIb	*diarizonae*
IV	*houtenae*
VI	*indica*

Salmonella bongori was originally designated *S. enterica* **subspecies V**. It has since been determined to be a separate species of *Salmonella*. However, for simplicity and convenience, these strains are commonly referred to as "subspecies V" for the purpose of serotype designation.

2) *Salmonella* Serotype Antigens

Salmonella serotype is based on the immunoreactivity of two surface structures, **O antigen** and **H antigen.**

O antigen is a carbohydrate antigen (also called a polysaccharide) that is the outermost component of LPS (lipopolysaccharide). It is a polymer of **O subunits**; each O subunit is typically composed of four to six sugars depending on the O antigen. Variation in O antigen results from variation in the sugar components of the O subunit, from variation in the nature of the covalent bond between the sugars of the subunit, and from variation in the nature of the linkage between the O subunits that form the O antigen polymer.
O antigens are designated by numbers and are divided into **O serogroups** or **O groups**. O groups are designated by the primary **O factor(s)** that are associated with the group. Many of the common O groups were originally designated by letter and are still commonly referred to by letter (e.g., *S*. Typhimurium belongs to Group O:4 or Group B, *S*. Enteritidis belongs to group O:9 or Group D1; *S*. Paratyphi A belongs to Group O:2 or Group A).

Additional O factors are associated with some O groups and are often variably present or variably expressed. Table 1 lists the O groups and the additional O antigens that may be present in serotypes of that group. When multiple O factors are present, they are listed sequentially and separated by commas.
H antigen is a protein antigen called flagellin; multiple flagellin subunits make up the filament component of the flagella. The ends of flagellin are conserved and give the flagella its characteristic filament structure. The antigenically variable portion of flagellin is the middle region, which is surface-exposed. Salmonella is unique among the enteric bacteria in that it can express two different flagellin antigens. Typically, this is coordinated so that only one antigen is expressed at time in a single bacterial cell. The two antigens are referred as Phase 1 and Phase 2. "Monophasic" isolates are those that

express only a single flagellin type. These occur naturally in some serotypes (e.g., S. Enteritidis, S. Typhi, most subspecies IIIa and IV serotypes), or can occur through the inactivation of the gene encoding the Phase 1 or Phase 2 antigen.

Table 2 lists the H antigens of Salmonella. Some antigens are composed of multiple factors, which are separated by commas; for example, the second phase antigen of S. Typhimurium is composed of factors 1 and 2, which is represented as "1,2". Related antigens are grouped into complexes.

3) Salmonella Serotype Identification

Salmonella serotypes are typically identified in a cascade of tests. First, an isolate is identified and the subspecies is determined, typically by biochemical testing. O antigens and H antigens are detected in independent agglutination assays using antisera that react with groups of related antigens or a single antigen. Both H antigens can sometimes be detected in a single culture, particularly for older strains or for isolates that have been passed multiple times. When only one H antigen is detected, the isolate is inoculated onto the top of a tube of phase reversal media, a semisolid media containing antisera to the H antigen that has already been identified. Organisms expressing the previously detected H antigen are immobilized by the added antisera and grow only at the top of the tube. Organisms expressing the second H antigen are able to move away from the top of tube, evidenced by growth throughout the tube. The second H antigen is then determined using organisms recovered from the bottom of the phase reversal media.

4) Salmonella Serotype Designation

All Salmonella serotypes can be designated by a formula. Additionally, subspecies I serotypes are given a name (e.g., Typhimurium, Enteritidis, Typhi, etc).

The typical format for a serotype formula is:
Subspecies [space] O antigens [colon] Phase 1 H antigen [colon] Phase 2 H antigen

Examples:

I 4,5,12:i:1,2 (S. Typhimurium)
I 4,12:i:1,2 (S. Typhimurium)
I 9,12:g,m:- (S. Enteritidis)
II 47:b:1,5 (S. II 47:b:1,5)
IV 48:g,z_{51}:- (S. IV 48:g,z_{51}:-)
IIIb 65:(k):z (S. IIIb 65:(k):z)

Other conventions:

* Some O and H factors are variably present. This is indicated in the generic serotype formula by underline when the factor is encoded on a bacteriophage (e.g., 1) or by square brackets (e.g., [5]) when the antigen is variably present. For an individual isolate, if the variable factor is detected it is included in the formula without additional notation. If the variable factor is not detected, it is not listed in the formula. Weakly recognized antigens are indicated by parentheses (e.g., (k)).
* The absence of an H antigen is indicated by a minus sign ("-") for the particular phase. For example, the "monophasic Group B" isolates that are becoming more common in the US are designated as "S. I 4,5,12:i:- " or "S. I 4,12:i:- ". Nonmotile isolates (express no H antigen) are indicated by minus signs in both phases, but can also be designated by "NM" or "nonmotile" in place of the H antigens.

* Isolates that do not express O antigen (rough isolates) or express a capsule that prevents immunologic detection of the O antigen (mucoid isolates) are indicated by "O-rough" or "Mucoid" in place of the O antigen.
* Rarely, isolates express a third H antigen that is noted by a colon followed by the antigen after the Phase 2 H antigen (e.g., S. II 13,23:b:[1,5]:z42, formerly S. Acres)

5) Salmonella Serotype Statistics

There were 2501 Salmonella serotypes as of 2001; approximately 60% belong to subspecies I. In the US, approximately 99% of reported human isolates belong to subspecies I. The "top 10" serotypes account for approximately 74% of all isolates reported in the US; the "top 100" serotypes account for about 98% of all isolates. Among the top 100 serotypes, only S. IV 48:g,z51:- (formerly S. Marina), S. IV 50:z4,z23:- (formerly S. Flint), S. IV 6,7:z4,z24:- (formerly S. Kralendyk), and S. IV 16:z4,z32:- (formerly S. Chameleon) are not subspecies I. Among the non-subspecies I isolates, subspecies IV isolates are the most common, followed by subspecies II, IIIa, and IIIb. Subspecies VI and S. bongori isolates are very rare.

6) Additional Reading

Brenner, F. W., R. G. Villar, F. J. Angulo, R. Tauxe, and B. Swaminathan.. 2000. Salmonella nomenclature. J Clin Microbiol 38: 2465-2467 [http://jcm.asm.org/cgi/reprint/38/7/2465.pdf]

Brenner, F. W., and A. C. McWhorter-Murlin. 1998. Identification and Serotyping of Salmonella. Centers for Disease Control and Prevention, Atlanta, GA.

Popoff, M. Y. 2001. Antigenic Formulas of the Salmonella Serovars, 8th edition. WHO Collaborating Centre for Reference and Research on Salmonella, Pasteur Institute, Paris, France.

Popoff, M. Y., J. Bockemuhl, F. W. Brenner, and L. L. Gheesling. 2001. Supplement 2000 (no. 44) to the Kauffmann-White scheme. Res. Microbiol. 152:907-909.

For questions or additional information, please contact Patti Fields [(404) 639-1748; pif1@cdc.gov]

[1] According to the Bacteriological Code, the legitimate species name for S. enterica is S. choleraesuis, and there are a few other differences from the nomenclature described. The official taxonomic designations are confusing and proposals to change them are currently under consideration. The taxonomy described here is used by most laboratories worldwide, including the CDC.

Appendix IX: Overview of *Salmonella* Serotype Designation

Table 1. Antigens associated with *Salmonella* O serogroups

O Group (number designation)	O Group (letter designation)	Antigens present in all serotypes	Additional antigens that may be present in some serotypes
2	A	2,12	1
4	B	4,12	1; 5; 27
7	C1	6,7	14; (Vi)
8	C2	8	6; 20
9	D1	9,12	1; (Vi)
9,46	D2	9,46	none
9,46,27	D3	9,12,46,27	1
3,10	E1	3,10	15; 15,34
1,3,19	E4	1,3,19	10; 15
11	F	11	none
13	G	13	1; 22; 23
6,14	H	6,14	1; 24; 25
16	I	16	none
17	J	17	none
18	K	18	6; 14
21	L	21	none
28	M	28	none
30	N	30	none
35	O	35	none
38	P	38	none
39	Q	39	none
40	R	40	1
41	S	41	none
42	T	42	1
43	U	43	none
44	V	44	1
45	W	45	none
47	X	47	1
48	Y	48	none
50	Z	50	none
51		51	1
52		52	none
53		53	1
54 (provisional)		54	21; 3; 3,15; 4,12; 8,20; 6,7
55		55	none
56		56	none
57		57	none
58		58	none
59		59	1
60		60	none
61		61	none
62		62	none
63		63	none
65		65	none
66		66	none
67		67	none

Appendix IX: Overview of *Salmonella* Serotype Designation

Table 2. H (flagellar) antigens of *Salmonella*

1 complex:		Other antigens (not part of a complex):
	1,2	a
	1,5	b
	1,6	c
	1,7	d
	1,2,5	e,h
	1,2,7	i
	1,5,7	k
	1,6,7	(k)
EN complex:	e,n,x	r
	e,n,x,z15	r,i
	e,n,z15	y
G complex:	f,g	z
	f,g,m,t	z6
	f,g,s	z10
	f,g,t	z29
	g,m	z35
	g,m,p,s	z36
	g,m,q	z36,z38
	g,m,s	z38
	g,m,s,t	z39
	g,m,t	z41
	g,p	z42
	g,p,s	z44
	g,p,u	z47
	g,q	z50
	g,s,q	z52
	g,s,t	z53
	g,t	z54
	g,z51	z55
	g,z62	z56
	g,z63	z57
	g,z85	z60
	m,p,t,u	z61
	m,t	z64
L complex:	l,v	z65
	l,w	z67
	l,z13	z68
	l,z13,z28	z69
	l,z28	z71
Z4 complex:	z4,z23	z81
	z4,z23,z32	z83
	z4,z24	z87
	z4,z32	z88

Appendix X: *Salmonella* Typhi Case Report Form

Retrieve Data | Reset Radio Buttons | Reset Form

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta, Georgia 30333

TYPHOID FEVER SURVEILLANCE REPORT

CDC NO.: (1-5)

Form Approved OMB No. 0920-0009

Instructions:
– Please complete this form only for new, symptomatic, culture-proven cases of typhoid fever. –

DEMOGRAPHIC DATA

1. Reporting State: (6-7)
2. First three letters of patient's last name: (8-10)
3. Date of birth: Mo. Day Yr. (11-16) or Age: (in years) (17-18)
4. Sex: (19) 1 Male 2 Female
5. Does the patient work as a food handler? (20) 1 Yes 2 No 9 Unk.
6. Citizenship: (21) 1 U.S. 2 Other: 9 Unk.

CLINICAL DATA

7. Was the patient ill with typhoid fever? (fever, abdominal pain, headache, etc) (22) 1 Yes 2 No 9 Unk.
If Yes, give date of onset of symptoms: Mo. Day Yr. (23-28)
8. Was the patient hospitalized? (29) 1 Yes 2 No 9 Unk.
If Yes, how many days was the patient hospitalized? Days (30-31)
9. Outcome of case: (32) 1 Recovered 2 Died 9 Unk.

LABORATORY DATA

10. Date *Salmonella typhi* first isolated: Mo. Day Yr. (33-38)
Site(s) of isolation: *(check all that apply)* (39) 1 Blood 2 Stool 3 Gall bladder 4 Other (specify): (40-65)

11. Was **antibiotic sensitivity testing** performed on this (these) isolate(s) at the laboratory? *(Please contact the clinical laboratory for this information)* (56) 1 Yes 2 No 9 Unk.
If Yes, was the organism **resistant** to:
- Ampicillin: 1 Yes 2 No 8 Not tested
- Chloramphenicol: 1 Yes 2 No 8 Not tested
- Trimethoprim-sulfamethoxazole: 1 Yes 2 No 8 Not tested
- Fluoroquinolones (e.g., Ciprofloxacin): 1 Yes 2 No 8 Not tested

EPIDEMIOLOGIC DATA

12. Did this case occur as part of an outbreak? (two or more cases of typhoid fever associated by time and place) 1 Yes 2 No 9 Unk.

13. Did the patient receive typhoid vaccination (primary series or booster) within **five years** before onset of illness? 1 Yes 2 No 9 Unk.
If Yes, indicate type of vaccine received: Year received:
- Standard killed typhoid shot (Wyeth-Ayerst): 1 Yes 2 No 9 Unk.
- Oral Ty21a or Vivotif (Berna) four pill series: 1 Yes 2 No 9 Unk.
- ViCPS or Typhim Vi shot (Pasteur Merieux): 1 Yes 2 No 9 Unk.

14. Did the patient travel or live outside the United States during the 30 days before the illness began? (77) 1 Yes 2 No 9 Unk.
If Yes, please list in order the countries visited during the 30 days before the illness began: (other than the United States)
1. 2. 3. 4.
Date of most recent return or entry to the United States: Mo. Day Yr.

15. Was the purpose of the international travel:
a.) Business? 1 Yes 2 No 9 Unk.
b.) Tourism? 1 Yes 2 No 9 Unk.
c.) Visiting relatives or friends? 1 Yes 2 No 9 Unk.
d.) Immigration to U.S.? 1 Yes 2 No 9 Unk.
e.) Other? 1 Yes 2 No 9 Unk.
(If other, specify):

16. Was the case traced to a typhoid carrier? 1 Yes 2 No 9 Unk.
If Yes, was the carrier **previously known** to the health department? 1 Yes 2 No 9 Unk.

17. Comments:

18. Name of Person Completing Form:
Address:
Telephone:
Date: Mo. Day Yr.

– THANK YOU VERY MUCH FOR TAKING THE TIME TO COMPLETE THIS FORM –

Please send a copy to your State Epidemiology Office *and the* Foodborne and Diarrheal Diseases Branch, Centers for Disease Control and Prevention, Mailstop A-38, Atlanta, Georgia, 30333. • Fax: (404) 639-2205

Public reporting burden of this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-24, Atlanta, Georgia 30333; ATTN: PRA (0920-0009).

CDC 52.5 (E), rev. (CDC Adobe Acrobat 5.0 Electronic Version, 1/2003) | Save Data | TYPHOID FEVER SURVEILLANCE REPORT | Print | Email Form | Page 1 of 1

Can be accessed at: http://basis1.cdc.gov/BASIS/masompb/forms/eforms/DDD/563

Appendix XI: *Cholera* and other *Vibrio* Illness Surveillance Report

PATIENT'S NAME:	TEL.: Home ( ) Work ( )
ADDRESS:	
PHYSICIAN'S NAME:	TEL.: ( )

– PATIENT IDENTIFIERS NOT TRANSMITTED TO CDC –

SEND COMPLETED REPORT TO STATE INFECTION CONTROL

CDC CENTERS FOR DISEASE CONTROL AND PREVENTION

CHOLERA AND OTHER VIBRIO ILLNESS SURVEILLANCE REPORT

State will forward to: Centers for Disease Control and Prevention, Foodborne and Diarrheal Diseases Branch M/S A38, 1600 Clifton Road, Atlanta, GA 30333

OMB 0920-0322 Exp. Date 12/31/2002

I. DEMOGRAPHIC AND ISOLATE INFORMATION

1. First three letters of patients first name: (1-3)

REPORTING HEALTH DEPARTMENT

State: (4-5) | City: (6-15) | County/Parish: (16-26)

State No.: (27-37) | CDC USE ONLY (38-48) | FDA No.: (49-57)

2. Date of birth: Mo. Day Yr. (58-63)

3. Age: Years Mos. (64-67)

4. Sex: (68) ☐ M (1) ☐ F (2) ☐ Unk. (9)

5. Race/Ethnicity: (69) ☐ White (not Hispanic) (1) ☐ Black (not Hispanic) (2) ☐ Hispanic (3) ☐ Asian/Pacific Islander (4) ☐ American Indian/Alaska Native (5) ☐ Other: _____ (6) ☐ Unk. (9)

6. Occupation: (70-81) _____

7. *Vibrio* species isolated (check one or more):

Species	Source of specimen(s) collected from patient: Stool	Blood	Wound	Other	Date specimen collected (If more than one specify earliest date): Mo. Day Yr.	If wound or other, specify site:
☐ *V. alginolyticus*	☐ (82)	☐ (83)	☐ (84)	☐ (85)	(86-91)	(92-103)
☐ *V. cholerae* O1	☐ (104)	☐ (105)	☐ (106)	☐ (107)	(108-113)	(114-125)
☐ *V. cholerae* O139	☐ (126)	☐ (127)	☐ (128)	☐ (129)	(130-135)	(136-147)
☐ *V. cholerae non-O1, non-O139*	☐ (148)	☐ (149)	☐ (150)	☐ (151)	(152-157)	(158-169)
☐ *V. cincinnatiensis*	☐ (170)	☐ (171)	☐ (172)	☐ (173)	(174-179)	(180-191)
☐ *V. damsela*	☐ (192)	☐ (193)	☐ (194)	☐ (195)	(196-201)	(202-213)
☐ *V. fluvialis*	☐ (214)	☐ (215)	☐ (216)	☐ (217)	(218-223)	(224-235)
☐ *V. furnissii*	☐ (236)	☐ (237)	☐ (238)	☐ (239)	(240-245)	(246-257)
☐ *V. hollisae*	☐ (258)	☐ (259)	☐ (260)	☐ (261)	(262-267)	(268-279)
☐ *V. metschnikovii*	☐ (280)	☐ (281)	☐ (282)	☐ (283)	(284-289)	(290-301)
☐ *V. mimicus*	☐ (302)	☐ (303)	☐ (304)	☐ (305)	(306-311)	(312-323)
☐ *V. parahaemolyticus*	☐ (324)	☐ (325)	☐ (326)	☐ (327)	(328-333)	(334-345)
☐ *V. vulnificus*	☐ (346)	☐ (347)	☐ (348)	☐ (349)	(350-355)	(356-367)
☐ *Vibrio* species - not identified	☐ (368)	☐ (369)	☐ (370)	☐ (371)	(372-377)	(378-389)
☐ Other (specify): _____ (390-405)	☐ (406)	☐ (407)	☐ (408)	☐ (409)	(410-415)	(416-427)

8. Were other organisms isolated from the same specimen that yielded *Vibrio*? Yes (1) ☐ No (2) ☐ Unk. (9) ☐ (428)

Specify organism(s): _____ (429-450)

9. Was the identification of the species of *Vibrio* (e.g., *vulnificus*, *fluvialis*) confirmed at the State Public Health Laboratory? Yes (1) ☐ No (2) ☐ Unk. (9) ☐ (451)

10. Complete the following information if the isolate is *Vibrio cholerae* O1 or O139:

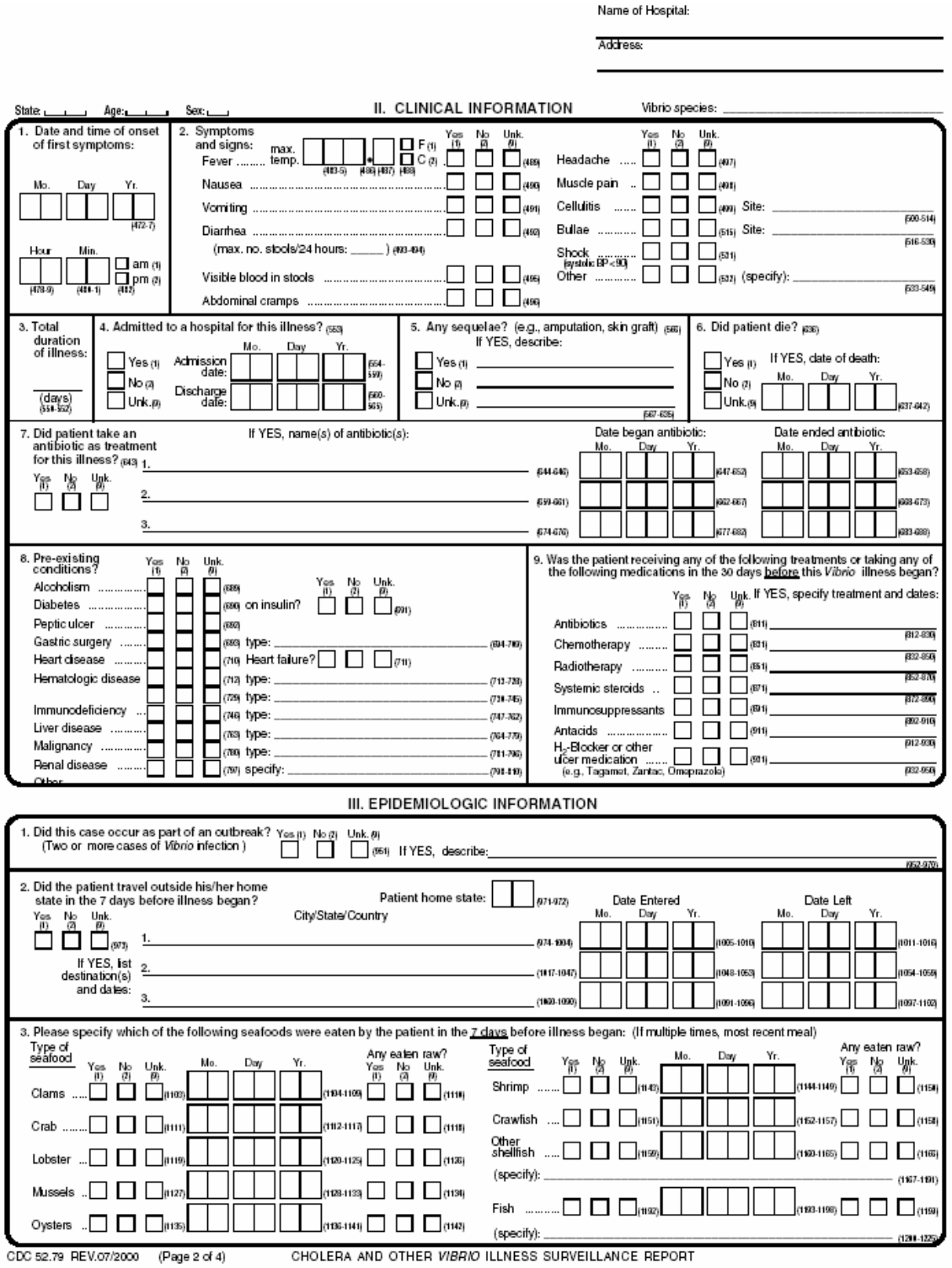
Serotype (452) (check one): ☐ Inaba (1) ☐ Ogawa (2) ☐ Hikojima (3) ☐ Not Done (4) ☐ Unk. (9)

Biotype (453) (check one): ☐ El Tor (1) ☐ Classical (2) ☐ Not Done (3) ☐ Unk. (9)

Toxigenic? (454) (check one): Yes (1) ☐ No (2) ☐ Unk. (9) ☐

If YES, toxin positive by: (check all that apply) ☐ ELISA (455) ☐ Latex agglutination (456) ☐ Other (specify): _____ (457-471)

Appendix XI: *Cholera* and other *Vibrio* Illness Surveillance Report



Name of Hospital:

Address:

State: Age: Sex:

II. CLINICAL INFORMATION

Vibrio species:

1. Date and time of onset of first symptoms:
Mo. Day Yr. (472-7)
Hour Min. am (1) pm (2) (478-9) (480-1) (482)

2. Symptoms and signs:
Fever ..... max. temp. (483-5) . (486) F (1) C (2) (487) (488)
Nausea ..... (490)
Vomiting ..... (491)
Diarrhea ..... (492)
(max. no. stools/24 hours: _____) (493-494)
Visible blood in stools ..... (495)
Abdominal cramps ..... (496)
Headache ..... (497)
Muscle pain ..... (498)
Cellulitis ..... (499) Site: (500-514)
Bullae ..... (515) Site: (516-530)
Shock (systolic BP<90) ..... (531)
Other ..... (532) (specify): (533-549)
Yes (1) No (2) Unk. (9)

3. Total duration of illness: (days) (550-552)

4. Admitted to a hospital for this illness? (553)
Yes (1) No (2) Unk. (9)
Admission date: Mo. Day Yr. (554-559)
Discharge date: Mo. Day Yr. (560-565)

5. Any sequelae? (e.g., amputation, skin graft) (566)
If YES, describe:
Yes (1) No (2) Unk. (9) (567-626)

6. Did patient die? (636)
Yes (1) No (2) Unk. (9)
If YES, date of death: Mo. Day Yr. (637-642)

7. Did patient take an antibiotic as treatment for this illness? (643) Yes (1) No (2) Unk. (9)
If YES, name(s) of antibiotic(s):
1. (644-646)
2. (659-661)
3. (674-676)
Date began antibiotic: Mo. Day Yr.
(647-652) (662-667) (677-682)
Date ended antibiotic: Mo. Day Yr.
(653-658) (668-673) (683-688)

8. Pre-existing conditions? Yes (1) No (2) Unk. (9)
Alcoholism ..... (689)
Diabetes ..... (690) on insulin? (691)
Peptic ulcer ..... (692)
Gastric surgery ..... (693) type: (694-709)
Heart disease ..... (710) Heart failure? (711)
Hematologic disease (712) type: (713-728)
(729) type: (730-745)
Immunodeficiency ... (746) type: (747-762)
Liver disease ..... (763) type: (764-779)
Malignancy ..... (780) type: (781-796)
Renal disease ..... (797) specify: (798-813)
Other

9. Was the patient receiving any of the following treatments or taking any of the following medications in the 30 days before this *Vibrio* illness began?
Yes (1) No (2) Unk. (9) If YES, specify treatment and dates:
Antibiotics ..... (811) (812-831)
Chemotherapy ..... (831) (832-851)
Radiotherapy ..... (851) (852-871)
Systemic steroids .. (871) (872-891)
Immunosuppressants (891) (892-910)
Antacids ..... (911) (912-930)
H_2-Blocker or other ulcer medication ..... (931) (932-950)
(e.g., Tagamet, Zantac, Omeprazole)

III. EPIDEMIOLOGIC INFORMATION

1. Did this case occur as part of an outbreak? (Two or more cases of *Vibrio* infection) Yes (1) No (2) Unk. (9) (951) If YES, describe: (952-970)

2. Did the patient travel outside his/her home state in the 7 days before illness began? Yes (1) No (2) Unk. (9) (971)
Patient home state: (972-973)
If YES, list destination(s) and dates:
City/State/Country
1. (974-1004)
2. (1017-1047)
3. (1030-1060)
Date Entered: Mo. Day Yr.
(1005-1010) (1048-1053) (1061-1066)
Date Left: Mo. Day Yr.
(1011-1016) (1054-1059) (1067-1102)

3. Please specify which of the following seafoods were eaten by the patient in the 7 days before illness began: (If multiple times, most recent meal)

Type of seafood	Yes (1)	No (2)	Unk. (9)	Mo. Day Yr.	Any eaten raw? Yes (1)	No (2)	Unk. (9)
Clams	(1103)			(1104-1109)	(1110)		
Crab	(1111)			(1112-1117)	(1118)		
Lobster ...	(1119)			(1120-1125)	(1126)		
Mussels ..	(1127)			(1128-1133)	(1134)		
Oysters ..	(1135)			(1136-1141)	(1142)		

Type of seafood	Yes (1)	No (2)	Unk. (9)	Mo. Day Yr.	Any eaten raw? Yes (1)	No (2)	Unk. (9)
Shrimp	(1143)			(1144-1149)	(1150)		
Crawfish	(1151)			(1152-1157)	(1158)		
Other shellfish	(1159)			(1160-1165)	(1166)		
(specify):				(1167-1191)			
Fish	(1192)			(1193-1198)	(1199)		
(specify):				(1200-1225)			

Appendix XI: *Cholera* and other *Vibrio* Illness Surveillance Report

State: ___ Age: ___ Sex: ___

III. EPIDEMIOLOGIC INFORMATION (CONT.)

Vibrio species: _____

4. In the 7 days before illness began, was patient's skin exposed to any of the following?

	Yes (1)	No (2)	Unk. (9)	
A body of water (fresh, salt, or brackish water)	☐	☐	☐	(1226)
Drippings from raw or live seafood	☐	☐	☐	(1227)
Other contact with marine or freshwater life	☐	☐	☐	(1228)

If YES, specify body of water location: _____ (1229-1242)

Date of exposure: Mo. ☐☐ Day ☐☐ Yr. ☐☐ (1250-5)

Time of exposure: Hour ☐☐ (1256-7) Min. ☐☐ (1258-9) ☐ am (1) ☐ pm (2) (1260)

If YES to any of the above, answer each:

	Yes (1)	No (2)	Unk. (9)	
Handling/cleaning seafood	☐	☐	☐	(1243)
Swimming/diving/wading	☐	☐	☐	(1244)
Walking on beach/shore/ fell on rocks/shells	☐	☐	☐	(1245)
Boating/skiing/surfing	☐	☐	☐	(1246)
Construction/repairs	☐	☐	☐	(1247)
Bitten/stung	☐	☐	☐	(1248)
Other: (specify) _____	☐	☐	☐	(1249)

(1261-1275)

- If skin was exposed to water, indicate type: (1276)

☐ Salt (1) ☐ Brackish (3) ☐ Unk. (9)
☐ Fresh (2) ☐ Other (8) (specify): _____ (1277-1284)

Additional comments: _____ (1285-1290)

- If skin was exposed, did the patient sustain a wound during this exposure, or have a pre-existing wound? (choose one): (1291)

☐ YES, sustained a wound. (1) ☐ YES, had a pre-existing wound. (2) ☐ YES, uncertain if wound new or old. (3) ☐ NO. (4) ☐ Unk . (9)

If YES, describe how wound occurred and site on body :
(Note: Skin bullae that appear as part of the acute illness should be recorded in section II, Clinical Information, only).

_____ (1292-1320)

If isolate is *Vibrio cholerae* O1or O139 please answer questions 5 - 8.

5. If patient was infected with *V. cholerae* O1 or O139, to which of the following risks was the patient exposed in the 4 days before illness began:

	Yes (1)	No (2)	Unk. (9)	
Raw seafood	☐	☐	☐	(1321)
Cooked seafood	☐	☐	☐	(1322)
Foreign travel	☐	☐	☐	(1323)
Other person(s) with cholera or cholera-like illness	☐	☐	☐	(1324)
Street-vended food	☐	☐	☐	(1325)
Other	☐	☐	☐	(1326)

(specify): _____ (1327-1350)

6. If answered "yes" to foreign travel (question III. 5), had the patient been educated in cholera prevention measures before travel? Yes (1) ☐ No (2) ☐ Unk. (9) ☐ (1351)

If YES, check all source(s) of information received:

☐ Pre-travel clinic (1352) ☐ Friends (1355) ☐ Travel agency (1358)
☐ Airport (departure gate) (1353) ☐ Private physician (1356) ☐ CDC travelers' hotline (1359)
☐ Newspaper (1354) ☐ Health department (1357) ☐ Other (specify): (1360) _____ (1361-1400)

7. If answered "yes" to foreign travel (question III. 5), what was the patient's reason for travel? (check all that apply)

☐ To visit relatives/friends (1401)
☐ Business (1402)
☐ Tourism (1412)
☐ Military (1406)
☐ Other (specify): (1405) _____ (1406-1426)
☐ Unk. (1427)

8. Has patient ever received a cholera vaccine? Yes (1) ☐ No (2) ☐ Unk. (9) ☐ (1428)

(If YES, specify type most recently received):

☐ Oral (1429) ☐ Parenteral (1430)

Most recent date: Mo. ☐☐ Day ☐☐ Yr. ☐☐ (1431-1436)

If domestically acquired illness due to <u>any</u> *Vibrio* species is suspected to be related to seafood consumption, please complete section IV (Seafood Investigation).

ADDITIONAL INFORMATION or COMMENTS

_____

CDC Use Only
Source: (1443) ☐
Comment: (1444-1454) _____

Person completing section I - III: _____ Date: Mo. ☐☐ Day ☐☐ Yr. ☐☐ (1437-1442)

Syndrome: (1455) ☐

CDC Isolate No. _____ (1456-1462)

Title/Agency: _____ Tel.: ( ) _____

Appendix XI: *Cholera* and other *Vibrio* Illness Surveillance Report

State: ____ Age: ____ Sex: ____

IV. SEAFOOD INVESTIGATION SECTION

Vibrio species: _____

For each seafood ingestion investigated, please complete as many of the following questions as possible.
(Include additional pages section IV if more than one seafood type was ingested and investigated.)

1. Type of seafood (e.g., clams): _____ (1464-1480)
Date consumed: Mo. Day Yr. (1481-1486)
Time consumed: Hour Min. ☐ am (1) ☐ pm (2) (1487-8) (1489-90) (1491)
Amount consumed: _____ (1492-1512)

If patient ate multiple seafoods in the 7 days before onset of illness, please note why this seafood was investigated (e.g.,consumed raw, implicated in outbreak investigation):

_____

2. How was this fish or seafood prepared? (1513)
☐ Raw (1) ☐ Baked (2) ☐ Boiled (3) ☐ Broiled (4) ☐ Fried (5) ☐ Steamed (6) ☐ Unk. (9) ☐ Other (8) (specify): _____ (1514-1530)

3. Was seafood imported from another country? Yes (1) ☐ No (2) ☐ Unk. (9) ☐ (1531) If YES, specify exporting country if known: _____ (1532-1554)

4. Was this fish or shellfish harvested by the patient or a friend of the patient? Yes (1) ☐ No (2) ☐ Unk. (9) ☐ (1555) (If YES, go to question 12.)

5. Where was this seafood obtained? (1556) (Check one)
☐ Oyster bar or restaurant (1) ☐ Seafood market (4) ☐ Unk. (9)
☐ Truck or roadside vendor (2) ☐ Other (8)
☐ Food store (3) (specify): _____ (1557-1590)

6. Name of restaurant, oyster bar, or food store: _____ Tel.: ( )
Address: _____

7. If oysters, clams, or mussels were eaten, how were they distributed to the retail outlet? (1591)
☐ Shellstock (sold in the shell) (1) ☐ Shucked (2) ☐ Unk. (9) ☐ Other (8) (specify): _____ (1592-1610)

8. Date restaurant or food outlet received seafood: Mo. Day Yr. (1611-1616)

9. Was this restaurant or food outlet inspected as part of this investigation? Yes (1) ☐ No (2) ☐ Unk. (9) ☐ (1617)

10. Are shipping tags available from the suspect lot? (1618) Yes (1) ☐ No (2) ☐ Unk. (9) ☐
(Attach copies if available)

11. Shippers who handled suspected seafood: (please include certification numbers if on tags)
_____

12. Source(s) of seafood:
_____

13. Harvest site: _____ (1619-1639) Date: Mo. Day Yr. (1640-1645) Status: (1646)
☐ Approved (1) ☐ Conditional (3)
☐ Prohibited (2) ☐ Other (8) (specify): _____ (1647-1693)

_____ (1687-1687) Mo. Day Yr. (1688-1693) (1694)
☐ Approved (1) ☐ Conditional (3)
☐ Prohibited (2) ☐ Other (8) (specify): _____ (1695-1714)

14. Physical characteristics of harvest area as close as possible to harvest date:

	Result		Date Measured Mo. Day Yr.
Maximum ambient temp. (1715-1719)		☐ F (1) ☐ C (2) (1719)	(1720-1725)
Surface water temp. (1726-1729)		☐ F (1) ☐ C (2) (1729)	(1729-1734)
Salinity (ppt) (1735-1736)			(1737-1742)
Total rainfall (inches in prev. 5 days) (1743-1744)			(1745-1750)
Fecal coliform count (1751-1755)			(1756-1761) (Attach copy of coliform data)

15. Was there evidence of improper storage, cross-contamination, or holding temperature at any point? Yes (1) ☐ No (2) ☐ Unk. (9) ☐ (1762) If YES, specify deficiencies:
_____

Person completing section IV: _____ Date: Mo. Day Yr. (1763-1768)

Title/Agency: _____ Tel.: ( )

CASE ID__ __ __ __ --____ -- __ __ __

Appendix XII: HUS Case Report Form

Hemolytic Uremic Syndrome Surveillance
State Department of Health

Case Report Form

Instructions: Complete the following by interviewing the attending physician and/or reviewing patient's medical record.

I. PATIENT IDENTIFICATION

1A. Patient name _____ (last) _____ (first) **2A. Date of birth** ____/____/____ (mo / day / yr)

3A. Parent/guardian _____ (last) _____ (first) **4A*. Medical Rec #** _____

5A. Address _____ (number/street) (city) (state) (zip)

6A. Phone home (____) _____ **7A. Phone work** (____) _____ **8A. County of residence** _____

9A*. Sex ☐ Female ☐ Male

10A. Ethnicity ☐ Hispanic ☐ Non-Hispanic ☐ Unknown

11A. Race ☐ White ☐ Asian / Pacific Islander ☐ Black ☐ American Indian / Alaska Native
☐ Other_____ ☐ Unknown

12A. Are you completing this form for a case identified by ICD9 code review of hospital discharge data?
- ☐ no (skip to 14A)
- ☐ yes

13A. Has this case been previously reported (either through the provider network or other source)?
- ☐ no ----> Complete questions marked by an asterisk (*) on forms A, B, and C
- ☐ yes ----> Stop here. Staple this form to patient' s original report, and update database, changing answers for this and the previous question (12A and 13A only) to "yes"

II. HOSPITAL INFORMATION

14A. Person reporting case _____ **15A. Phone** (_____)_____

16A. Attending physician _____ **17A. Phone** (_____)_____

18A*. Hospital _____ (Name) (City/State) **19A*. Phone** (_____)_____

20A*. Date of admission or transfer to this facility ____/____/____

21A*. Date of discharge or transfer from this facility ____/____/____ ☐ **Still hospitalized**

22A. Institution transferred to (if applicable) _____ (Name) (City/State)

23A. Institution where first hospitalized (if different) _____ (Name) (City/State)

24A. Date of initial hospitalization (if different) ____/____/____

25A. Physician, initial hospitalization (if different) _____ **26A. Phone** (_____)_____

Appendix XII: HUS Case Report Form

III. CLINICAL INFORMATION

27A*. Date of HUS diagnosis ____/____/____

28A*. Did patient have diarrhea during the 3 weeks before HUS diagnosis?.............☐ yes ☐ no ☐ unsure

if yes 29A.* Date of diarrhea onset _____/_____/_____

30A. Did stools contain visible blood at any time ....☐ yes ☐ no ☐ unsure

31A. Was diarrhea treated with antimicrobial medications...........☐ yes ☐ no ☐ unsure

if yes 31A-1. Type of antimicrobial ____

31A-2. Was patient treated with antimicrobial medications for any other reason than diarrhea during the 3 weeks before HUS diagnosis? ……………..........☐ yes ☐ no ☐ unsure

if yes 31A-3. Type of antimicrobial ____

31A-4. Reason(s)____

Other medical conditions present during 3 weeks before HUS diagnosis:

32A*. Urinary tract infection ....☐ yes ☐ no ☐ unsure

33A*. Respiratory tract infection ....☐ yes ☐ no ☐ unsure

34A*. Pregnancy ....☐ yes ☐ no ☐ unsure

35A*. Malignancy..☐ yes ☐ no ☐ unsure

36A*. Transplanted organ or bone marrow...☐ yes ☐ no ☐ unsure

37A*. HIV infection...☐ yes ☐ no ☐ unsure

Laboratory values within 7 days before and 3 days after HUS diagnosis:

38A*. Highest serum creatinine..______ mg/dL ☐ not done

39A. Highest serum BUN ....______ mg/dL ☐ not done

40A. Highest serum amylase..______ U/L ☐ not done

41A. Highest WBC ....______K/mm^3 ☐ not done

42A*. Lowest hemaglobin ....______ g/dL ☐ not done

or Lowest hematocrit ....______ % ☐ not done

43A*. Lowest platelet count ....______ K/mm^3 ☐ not done

Other laboratory findings within 7 days before and 3 days after HUS diagnosis:

44A*. Blood smear with microangiopathic changes (i.e., schistocytes, burr cells, helmet cells or red cell fragments)........................☐ yes ☐ no ☐ unsure ☐ not done

45A*. Blood in urine by dipstick...☐ yes ☐ no ☐ unsure ☐ not done

46A*. Protein in urine by dipstick...☐ yes ☐ no ☐ unsure ☐ not done

47A*. RBC in urine by microscopy..☐ yes ☐ no ☐ unsure ☐ not done

48A. Patient's blood type_______☐ unknown

To be completed by health department

49A. How was patient's illness <u>first</u> identified by health department?

- ☐ Report of HUS case by a participating* physician or service
- ☐ Report of HUS case by a non-participating physician or service
- ☐ Routine O157 surveillance
- ☐ Other, describe______________________________

*member of active HUS surveillance network

50A. Is this case outbreak related?................................. ☐yes ☐no ☐ unsure______

51A. Status of report ☐Initial ☐Update ☐Complete

52A. Date ____/____/____ 53A. Completed by (initials)________________

Revised 12/18/2003

CASE ID__ __ __ __ --__ __ -- __ __ __

B B

Appendix XIII: HUS Microbiology Report Form

Hemolytic Uremic Syndrome Surveillance
State Department of Health

Microbiology Report Form

Instructions: Complete by contacting microbiology laboratory at each institution where patient was treated. Complete one composite form for all laboratories.

1B. Patient name _____ (last) _____ (first) **2B. Date of birth** ____/____/___

3B*. Was stool specimen obtained from this patient ..... ☐ yes ☐ no ☐ unsure

if no, go to question 26B

4B. Laboratories where stool(s) tested

_____ (Name) _____ (City/State) **Phone (____) _____**

_____ (Name) _____ (City/State) **Phone (____) _____**

_____ (Name) _____ (City/State) **Phone (____) _____**

_____ (Name) _____ (City/State) **Phone (____) _____**

5B. Was stool tested for Shiga toxin .....☐ yes ☐ no ☐ unsure

if yes **6B. Methods(s)/kit(s) used**_____

7B. Result..... ☐ positive ☐ negative ☐ unsure

8B. Collection date 1st specimen tested: ____/____/____

9B. Collection date 1st positive specimen: ____/____/____

10B*. Was stool cultured for *E. coli* O157?.....…☐ yes ☐ no ☐ unsure

if no ***skip to question #6***

if yes **11B. Collection date 1st specimen tested for O157 ____/____/____**

12B. Methods used

☐ culture on sorbitol-MacConkey agar

☐ other, describe_____

13B. Was *E. coli* O157 isolated?.....☐ yes ☐ no ☐ unsure

if yes **14B. Collection date 1st positive specimen: ____/____/____**

15B. Result of H antigen testing *(check one)*:

☐ H7 positive ☐ other H, specify:_____

☐ H7 negative

☐ unsure or not tested

☐ non-motile

16B. Was non-O157 Shiga toxin-producing *E. coli* isolated.....☐ yes ☐ no ☐ unsure

if yes **17B. Serotype: O:____ H:____ ☐ non-motile ☐ unknown**

18B. Collection date 1st specimen tested: ____/____/____

19B. Collection date 1st positive specimen: ____/____/____

Revised 12/18/2003

CASE ID__ __ __ __ --__ __ -- __ __ __

B

Appendix XIII: HUS Microbiology Report Form

B

20B. Other pathogen isolated from stool.....☐ yes ☐ no ☐ unsure

if yes **21B. Pathogen #1_____ Specimen collection date ____/____/____**
22B. Pathogen #2_____ Specimen collection date ____/____/____

If O157 or other STEC was isolated, complete the following based on health department records:

23B. Disposition of isolate
- ☐ **Sent to state laboratory (reference # _____)**
- ☐ **Sent to CDC**
- ☐ **Sent to other reference laboratory (specify _____)**
- ☐ **Discarded**

24B. Identity of isolate confirmed by state Public Health Laboratory
- ☐ **yes**
- ☐ **no**
- ☐ **unsure**
- ☐ **not tested**

Comment_____

25B. PHLIS reference number:_____

26B. Has patient serum been tested for antibodies to O157 or other STEC?..... ☐ yes ☐ no ☐ unsure

if yes

27B. Serogroup O157	**Titers : IgG 1:____**	**Interpretation**	**☐ positive**	**☐ negative**	**☐ borderline**
	IgM 1:____	**Interpretation**	**☐ positive**	**☐ negative**	**☐ borderline**
28B. Serogroup O111	**Titers : IgG 1:____**	**Interpretation**	**☐ positive**	**☐ negative**	**☐ borderline**
	IgM 1:____	**Interpretation**	**☐ positive**	**☐ negative**	**☐ borderline**
29B. Serogroup O26	**Titers : IgG 1:____**	**Interpretation**	**☐ positive**	**☐ negative**	**☐ borderline**
	IgM 1:____	**Interpretation**	**☐ positive**	**☐ negative**	**☐ borderline**

30B. Status of report ☐ initial ☐ update ☐ complete

31B. Date ____/____/____ **32B. Completed by (initials) _____**

CASE ID__ __ __ __ --__ __ -- __ __ __

Appendix XIV: HUS Chart Review Form

Hemolytic Uremic Syndrome Surveillance
State Department of Health

Chart Review Form

Instructions: Complete after patient has been discharged; use hospital discharge summary, consultation notes and DRG coding sheet. Complete one composite form for all institution where hospitalized.

1C. Patient name _____ _____ **2C. Date of birth** ____/____/____
last first

3C. Hospitals admitted _____ **Phone** (____) _____
Date admitted above:____/____/___ **Date discharged above:**____/____/___

_____ **Phone** (____) _____
Date admitted above:____/____/___ **Date discharged above:**____/____/___

_____ **Phone** (____) _____
Date admitted above:____/____/___ **Date discharged above:**____/____/___

_____ **Phone** (____) _____
Date admitted above:____/____/___ **Date discharged above:**____/____/___

4C. Date of first admission:____/____/___ **5C. Date of last discharge:**____/____/___

Did any of the following complications occur during this admission:

							Date of onset
8C*	Pneumonia.....	☐ yes	☐ no	☐ unsure	9C.	*if yes*	___/___/___
10C*	Seizure.....	☐ yes	☐ no	☐ unsure	11C.	*If yes*	___/___/___
12C*	Paralysis or hemiparesis.....	☐ yes	☐ no	☐ unsure	13C.	*If yes*	___/___/___
14C*	Blindness.....	☐ yes	☐ no	☐ unsure	15C.	*if yes*	___/___/___
16C*	Positive blood culture.....	☐ yes	☐ no	☐ unsure	17C.	*if yes*	___/___/___

if yes, Pathogen(s) isolated: _____

18C*	Other major neurologic sequelae	☐ yes	☐ no	☐ unsure	19C.	*if yes*	___/___/___

if yes, Describe: _____

Were any of the following procedures performed during this admission:

20C*	Peritoneal dialysis.....	☐ yes	☐ no	☐ unsure
21C*	Hemodialysis.....	☐ yes	☐ no	☐ unsure
	Transfusion with:			
22C.	packed RBC or whole blood.....	☐ yes	☐ no	☐ unsure
23C.	platelets.....	☐ yes	☐ no	☐ unsure
24C.	fresh frozen plasma.....	☐ yes	☐ no	☐ unsure
25C*	Plasmapheresis	☐ yes	☐ no	☐ unsure
26C	Laparotomy or other abdominal surgery*.....	☐ yes	☐ no	☐ unsure
	*other than insertion of dialysis catheter			
27C	*if yes to surgery*, Describe: _____			

28C*. Condition at discharge.....		☐ dead		☐ alive
29C	*if dead*, Date deceased:____/____/____			
30C*	*if alive*, Requiring dialysis.....	☐ yes	☐ no	☐ unsure
31C*	With neurologic deficits.....	☐ yes	☐ no	☐ unsure

32C. Status of report ☐ **initial** ☐ **update** ☐ **complete**

33C. Date ___/___/___ **34C. Completed by (intials)**_____

Revised 12/03/2003

I. OBJECTIVES

1. Determine the incidence of HUS using population-based surveillance
2. Monitor long term trends in STEC infection using HUS incidence as a marker
3. Identify STEC strains that cause HUS in the United States and monitor changes in their frequency over time
4. Establish a platform for conducting future studies of HUS pathogenesis and treatment

II. BACKGROUND

Hemolytic uremic syndrome (HUS) is a life-threatening illness characterized by hemolytic anemia, thrombocytopenia, and acute renal failure. Approximately 90% of HUS cases in the United States are caused by infection with Shiga toxin-producing *Escherichia coli* (STEC). Although *E. coli* O157:H7 (O157) is the most easily and most frequently isolated, many other STEC serotypes can also cause HUS.

Efforts to control STEC infections and develop effective therapies for HUS have been hampered by the absence of reliable surveillance data. Rapidly changing culturing practices make it difficult to know if STEC infections are becoming more or less common in any given area. The role of non-O157 STEC as a cause of HUS in the United States is largely unexplored. Finally, attempts to evaluate new treatments for HUS have been hindered by the rarity of reported cases in any given area.

Active surveillance in defined populations will allow determination of the incidence rate of HUS and whether that rate is changing. Linking microbial diagnosis to this active surveillance will allow differentiation of illness caused by O157 and by other STECs, and therefore will both provide a way to validate O157 surveillance data and a way to detect increases in illness caused by other STECs.

III. METHODS

A. General

The HUS surveillance system will be based on specialty provider networks comprised of pediatric nephrologists. The system will be introduced as a component of the Foodborne Diseases Active Surveillance Network (FoodNet).

B. Personnel

Participating sites will appoint one or more persons to serve as the local HUS surveillance officer.

C. Case finding

1. Sites will establish a practitioner reporting network that includes all pediatric nephrologists practicing within the catchment area. These practitioners will be

asked to report promptly all cases of HUS. The HUS surveillance officer will contact these practitioners monthly to identify any unreported cases.

2. Where available, hospital discharge data tapes will be reviewed annually to evaluate completeness of reporting for pediatric cases and to identify cases of HUS among adults (defined here as persons ≥ 18 years old). A protocol will be developed for reporting cases identified retrospectively through hospital discharge data tapes.

3. All patients <18 years old who receive treatment for acute HUS within the catchment area will be entered into the surveillance system, regardless of state of residence or how they were identified by the health department. Cases residing outside the United States should not be entered.

4. Although a practitioner network is not being established to identify cases of HUS among adults (≥ 18 years old), surveillance officers may learn of such cases nevertheless. These cases should be evaluated and reported in the same manner as pediatric cases, provided there is a history of an associated diarrheal illness.

D. Case Reporting

1. General
   a The period of hospitalization is defined as the time during which the patient is continuously hospitalized for an acute illness leading to a diagnosis of HUS. Transfers between hospitals are considered part of the same hospitalization.
   b. The Case ID number will be assigned using the year of HUS diagnosis (first 4 digits), the state FIPS code (next 2 digits), and a sequential case number (last 3 digits). For example, the third case in California during 2000 would be assigned # 2000-06-003
   c. Data will be entered by each site into a database using the HUS data entry screens in Epi Info. The data will be transmitted to CDC as an e-mail attachment when a case is identified or new information is obtained for a reported case.

2. Case Report Form:
   a. This form collects demographic information and data needed to confirm the diagnosis of HUS. It should be completed as soon as possible after the case is identified.
   b. The information may be collected by interviewing the attending physician, their designate (e.g., infection control nurse), and / or by reviewing the patient's medical record. If the patient has been transferred between hospitals, it may be necessary to contact the referring (or receiving) physician. This

should be done even if the referring physician does not work within the formal FoodNet catchment area.

3. Microbiology Report Form
   a. This form collects information on specimens that may have been obtained as part of regular medical care.
   b. Upon learning of the case, the HUS surveillance officer will complete a composite form by contacting the microbiology laboratory at all institutions where the patient is or has been hospitalized during the course of the acute illness. If the patient is still hospitalized, the officer will contact the laboratory periodically until the patient is discharged to identify any subsequent specimens.
   c. One copy of the microbiology reporting form may be completed for each laboratory testing a stool specimen from the patient. This includes clinical reference labs, public health labs and laboratories located outside the formal catchment area. However, only one summary form should be entered into the database

4. Chart Review Form
   a. This form collects information on the outcome and complications of the patient's acute illness.
   b. Following discharge of the patient, the HUS surveillance officer should obtain a copy of the hospital discharge summary, consult notes, and the diagnostically related groups (DRG) coding sheet and use these to complete the form.
   c. One composite summary form should be completed for all institutions where the patient was admitted during the hospitalization period, including any hospitals located outside of the formal EIP/FoodNet catchment area.

E. Laboratory Testing

Serologic testing for O157 and/or non-O157 antigens is available at CDC. States requesting this service should submit sera to the foodborne and diarrheal diseases immunology laboratory.

Appendix XVI: Foodborne Diseases Active Surveillance Network (FoodNet) Data Use Policy

CDC's Emerging Infections Program
Foodborne Diseases Active Surveillance Network (FoodNet)
Data Use Policy

I understand that I am responsible for the integrity and management of these datasets. The datasets will not be provided to a third party without the permission of the FoodNet Steering Committee. In the spirit of collaboration, I agree to keep the FoodNet Steering Committee informed of the results of analyses. In accordance with the FoodNet publication guidelines, I will not distribute the results of these analyses, electronically or otherwise, in the form of a poster, abstract, manuscript, report, press release, or other public presentation without the approval of the FoodNet Steering Committee.

If you have any questions about the data use policy, please contact FoodNet at 404-371-5465 or mailto: foodnet@cdc.gov.

http://www.cdc.gov/foodnet

Appendix XVII: Foodborne Diseases Active Surveillance Network (FoodNet) Protocol Development and Publications Policy

Guidelines for publication of manuscripts, abstracts, or other external releases of scientific data: The FoodNet publication policy applies to all manuscripts, abstracts, or external releases of scientific data in which FoodNet collaborates or which are supported , in whole or in part, through CDC's EIP.

1. **Data from one site (site-specific projects or one site's data from a multi-site project):** Sites are encouraged to review their data frequently and to discuss interesting findings with the FoodNet Steering Committee. Although FoodNet Steering Committee approval is not required before a site (or a site and CDC) initiates an abstract, manuscript, or other external release of scientific data that is based on site-generated data, sites are strongly encouraged to inform the Steering Committee of such investigations prior to submission or external release. If the next FoodNet Steering Committee meeting is scheduled after the deadline for submission or external release of data, committee members may be contacted individually by telephone or e-mail. Sharing of such information will reduce duplicative efforts and may lead to useful additional collaborations.

2. **Aggregate data:** CDC, sites, USDA, and FDA are encouraged to review the aggregate data (defined as data from $\geq$2 sites) frequently and discuss interesting findings with the FoodNet Steering Committee. The FoodNet Steering Committee will ensure that aggregate data are analyzed and published in a timely and equitable manner, and will ensure high scientific standards.

    a. Proposals for data analysis and external releases of scientific data may be initiated by individuals at CDC, any of the sites, USDA, or FDA. Such proposals should be made available to the FoodNet Steering Committee at least 1 week prior to the next Steering Committee call (usually the second Thursday of the month). Leadership of any given project is open to discussion by the Steering Committee.

    b. The FoodNet Steering Committee will designate a "Study Team," usually of five or fewer (representing at least three sites) persons, to work on creating a study protocol. The person who presents the proposal to the FoodNet Steering Committee will usually be a member of the Study Team and, with FoodNet administrative support, will arrange the first meeting or conference call.

    c. At the first meeting or conference call, the study team will determine the "Team Leader." The Team Leader, with FoodNet administrative support, must be willing and able to lead protocol and questionnaire development, and schedule and conduct meetings or conference calls. If the original Team Leader is unable to continue in a leadership role, or if another team member emerges as the leader (for example, by heading the protocol development), a leadership change may occur. If such a change is endorsed by the Study Team, the change may proceed. If there is disagreement within the Study Team about such a change, the matter will be resolved by the FoodNet Steering Committee. Other changes in Study Team personnel will be handled by the Study Team with the Steering Committee resolving any disagreements.

    d. The Team Leader will be the principal investigator (PI). The decision of who is to be PI will be made no later than the initiation of the project or

study. The PI will have the right of first refusal to be lead author or presenter of primary work (that is, publication or presentation).

e. The Study Team will select an "Analytic Team," which might be a subset of the Study Team or might include other FoodNet staff from CDC, USDA, FDA, or the sites.

f. The final study design and questionnaire will be made available to each site, CDC, FDA, and USDA for comment before the study or analysis proceeds.

3. **Dataset distribution:** Once a proposal has been approved by the steering committee, the appropriate dataset will be forwarded to each collaborator of the Analytical Team. A data release agreement must be signed at the time of receipt of the dataset and will be kept on file at CDC.

4. **Authorship:**

a. All manuscripts and abstracts that include unpublished data from FoodNet will include at least one author from CDC, unless CDC declines. All manuscripts and abstracts that include unpublished data from a site in FoodNet will include at least one author from that site, unless that site declines. Additional authors from a site or CDC should reflect significant contributions made by these persons, as described in the "Uniform requirement of manuscripts submitted to biomedical journals" (NEJM 1991;324:424-428). The Study Team will be the nucleus of the author list, unless a Team member declines. The lead author will determine the order of authorship. The Steering Committee will resolve any differences of opinion in this listing.

b. "FoodNet Working Group" will be included as the last entry on the authorship line in all publications and an asterisk or footnote will refer to "Foodborne Diseases Active Surveillance Network Working Group" and a listing of names.

c. Every publication in which FoodNet collaborates or which is supported wholly or in part through FoodNet should acknowledge the project name in the manuscript text. A sample sentence might be "This work was conducted by the FoodNet project of the Emerging Infections Program Network." Publications should also acknowledge financial support by referring to the CDC Emerging Infections Program cooperative agreement number and by acknowledging support from other agencies as appropriate.

d. All manuscripts or abstracts that include data from FoodNet will follow CDC clearance guidelines, which include that all authors have time to review and comment on manuscripts and abstracts before they are put into clearance, and all manuscripts or abstracts are cleared by CDC.

5. **Timelines:** Timelines for the development of major publications will be drafted by the PI and will be listed on the Publications Spreadsheet. These timelines can include deadlines for analysis, abstract submission for a national meeting, outline of paper, first draft, draft acceptable for clearance, and final paper for submission. If deadlines are not met, the Steering Committee can open the paper to leadership by other investigators.